

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA,

Plaintiff, *ex rel.*

GEORGE MARKELSON, as Executor of
the Estate of STEPHEN MARKELSON,
Deceased, and PETER NADLER and
LORRAINE WATERS,

Plaintiffs-Relators,

v.

DAVID B. SAMADI, M.D., DAVID B.
SAMADI, M.D., P.C., LENOX HILL
HOSPITAL and NORTHWELL HEALTH,
INC.,

Defendants.

COMPLAINT

(FILED UNDER SEAL)

JURY TRIAL DEMANDED

Plaintiff UNITED STATES OF AMERICA, *ex rel.*, by Plaintiff-Relators GEORGE MARKELSON, as Executor of the Estate of STEPHEN MARKELSON, Deceased, and PETER NADLER and LORRAINE WATERS, by their attorneys, JOSEPH LANNI, ESQ., and THE JACOB D. FUCHSBERG LAW FIRM, L.L.P., complaining of the defendants, DAVID B. SAMADI, M.D., DAVID B. SAMADI, M.D., P.C., LENOX HILL HOSPITAL and NORTHWELL HEALTH, INC., respectfully shows to this Court and alleges, upon information and belief, as follows:

PARTIES

1. That at all times hereinafter mentioned, plaintiff-relator GEORGE MARKELSON, as Executor of the Estate of STEPHEN MARKELSON, Deceased, resides and is domiciled at 70 Shore Road, Westhampton, NY 11977.
2. That at all times hereinafter mentioned, plaintiff-relators PETER NADLER and LORRAINE WATERS reside and are domiciled at 160 East 84th St., Apt. 6J, New York, NY 10028.
3. That at all times hereinafter mentioned, plaintiff-relators GEORGE MARKELSON, as Executor of the Estate of STEPHEN MARKELSON, Deceased, and PETER NADLER and LORRAINE WATERS were and are residents and domiciles of the State of New York.
4. That at all times hereinafter mentioned, plaintiff-relators GEORGE MARKELSON, as Executor of the Estate of STEPHEN MARKELSON, Deceased, and PETER NADLER and LORRAINE WATERS, were and are citizens of the State of New York.
5. That at all times hereinafter mentioned, plaintiff-relators GEORGE MARKELSON¹, as Executor of the Estate of STEPHEN MARKELSON², Deceased, and PETER NADLER³ and LORRAINE WATERS, were and are citizens of the United States of America.

¹ This party is also variously referred to as “GEORGE MARKELSON”, and “plaintiff executor” *infra*.

² This person is also variously referred to as “STEPHEN MARKELSON”, “MARKELSON” and the “patient” *infra*.

³ This party is also variously referred to as “NADLER” and the “patient” *infra*.

6. That at all times hereinafter mentioned, defendant DAVID B. SAMADI, M.D., was and is a physician duly licensed to practice medicine in the State of New York.
7. That at all times hereinafter mentioned, defendant DAVID B. SAMADI, M.D., was and is a physician offering professional medical services and medical and urology care and treatment to the public and patients in general, including STEPHEN MARKELSON, now deceased, and PETER NADLER in the State of New York.
8. That at all times hereinafter mentioned, defendant DAVID B. SAMADI, M.D., was and is a physician offering professional medical services and medical and urology care and treatment to the public and patients in general, including STEPHEN MARKELSON and PETER NADLER, with offices located at 485 Madison Avenue, 21st Floor, New York, NY 10022.
9. That at all times hereinafter mentioned, defendant DAVID B. SAMADI, M.D., was and is a physician who held himself out to the general public, including STEPHEN MARKELSON and PETER NADLER as being competent and having expertise in the medical, surgical and urology diagnosis, care and treatment of patients, and as being able to treat patients in general, and STEPHEN MARKELSON, Deceased, and PETER NADLER in particular, in accordance with accepted standards of proper medical, surgical and urology practice as well as in accordance with all requirements of federal and state law.
10. That at all times hereinafter mentioned, defendant DAVID B. SAMADI, M.D., was and is a physician board certified in the field of urology.

11. That at all times hereinafter mentioned, defendant DAVID B. SAMADI, M.D., was and is affiliated with defendant LENOX HILL HOSPITAL and was authorized to provide care and treatment to patients at defendant LENOX HILL HOSPITAL and at health care facilities owned, operated, managed and controlled by defendants LENOX HILL HOSPITAL and NORTHWELL HEALTH, INC.
12. That at all times hereinafter mentioned, defendant DAVID B. SAMADI, M.D., was and is employed as a physician by defendant LENOX HILL HOSPITAL.
13. That at all times hereinafter mentioned, defendant DAVID B. SAMADI, M.D., was and is an agent of defendant LENOX HILL HOSPITAL.
14. That at all times hereinafter mentioned, defendant DAVID B. SAMADI, M.D., was and is employed as a physician by defendant NORTHWELL HEALTH, INC.
15. That at all times hereinafter mentioned, defendant DAVID B. SAMADI, M.D.,⁴ was and is an agent of defendant NORTHWELL HEALTH, INC.
16. That at all times hereinafter mentioned, defendant DAVID B. SAMADI, M.D., was and is the owner and sole shareholder of a business entity known as DAVID B. SAMADI, M.D., P.C.
17. That at all times hereinafter mentioned, defendant DAVID B. SAMADI, M.D., owns, operates, controls, manages and directs a business entity known as defendant DAVID B. SAMADI, M.D., P.C.
18. That at all times hereinafter mentioned, defendant DAVID B. SAMADI, M.D., also was and is an employee of defendant DAVID B. SAMADI, M.D., P.C.

⁴ This party is also variously referred to as “DAVID SAMADI”, “SAMADI, M.D.”, and “SAMADI” *infra*.

19. That at all times hereinafter mentioned, defendant DAVID B. SAMADI, M.D., was and is an agent of defendant DAVID B. SAMADI, M.D., P.C.
20. That at all times hereinafter mentioned, defendant DAVID B. SAMADI, M.D., was and is affiliated with defendant LENOX HILL HOSPITAL and was and is authorized to provide care and treatment to patients at this hospital.
21. That at all times hereinafter mentioned, defendant DAVID B. SAMADI, M.D., was and is employed as a physician by defendant LENOX HILL HOSPITAL.
22. That at all times hereinafter mentioned, defendant DAVID B. SAMADI, M.D., was and is an agent of defendant LENOX HILL HOSPITAL.
23. That at all times hereinafter mentioned, defendant DAVID B. SAMADI, M.D., was and is the chairman of the urology department at defendant LENOX HILL HOSPITAL.
24. That at all times hereinafter mentioned, defendant DAVID B. SAMADI, M.D., was and is the director of the urology residency program at defendant LENOX HILL HOSPITAL.
25. That at all times hereinafter mentioned, defendant DAVID B. SAMADI, M.D., was and is party to an employment contract with defendant LENOX HILL HOSPITAL.
26. That at all times hereinafter mentioned, defendant DAVID B. SAMADI, M.D., was and is affiliated with defendant NORTHWELL HEALTH, INC., and was authorized to provide care and treatment to patients at hospital and health care facilities owned, operated, directed, managed and controlled by defendant NORTHWELL HEALTH, INC.

27. That at all times hereinafter mentioned, defendant DAVID B. SAMADI, M.D., was and is employed as a physician by defendant NORTHWELL HEALTH, INC.
28. That at all times hereinafter mentioned, defendant DAVID B. SAMADI, M.D., was and is an agent of defendant NORTHWELL HEALTH, INC.
29. That at all times hereinafter mentioned, defendant DAVID B. SAMADI, M.D., was and is party to an employment contract with defendant NORTHWELL HEALTH, INC.
30. That at all times hereinafter mentioned, defendant DAVID B. SAMADI, M.D., P.C., was and is a professional corporation duly organized and existing pursuant to the laws of the State of New York.
31. That at all times hereinafter mentioned, defendant DAVID B. SAMADI, M.D., P.C., was and is a professional corporation with its principal place of business and principal executive offices located at 485 Madison Avenue, 21st Floor, New York, NY 10022.
32. That at all times hereinafter mentioned, defendant DAVID B. SAMADI, M.D., P.C.,⁵ was and is a professional corporation with business operations, including a medical office, located at 485 Madison Avenue, 21st Floor, New York, NY 10022.
33. That at all times hereinafter mentioned, defendant LENOX HILL HOSPITAL was and is a purported domestic “not-for-profit” corporation duly organized and existing pursuant to the laws of the State of New York.

⁵ This party is also variously referred to as “DAVID SAMADI, P.C.”, and “SAMADI, P.C.,” *infra*.

34. That at all times hereinafter mentioned, defendant LENOX HILL HOSPITAL was and is a corporation with its principal place of business and principal executive offices located at 100 East 77th St. New York, NY 10075.
35. That at all times hereinafter mentioned, defendant LENOX HILL HOSPITAL was and is a corporation with business operations, including a hospital and health care facility, located at 100 East 77th St. New York, NY 10075.
36. That at all times hereinafter mentioned, defendant LENOX HILL HOSPITAL⁶ was and is a teaching hospital with ACGME certified and approved residency and fellowship training programs in various medical and surgical specialties, including a urology residency program.
37. That at all times hereinafter mentioned, defendant NORTHWELL HEALTH, INC., (i.e., NORTHWELL) was and is a corporation duly organized and existing pursuant to the laws of the State of New York.
38. That at all times hereinafter mentioned, defendant NORTHWELL HEALTH, INC., was and is a purported domestic “not-for-profit” corporation with its principal place of business and principal executive offices located at 145 Community Drive, Great Neck, NY 11021.
39. That at all times hereinafter mentioned, defendant NORTHWELL HEALTH, INC., was and is a corporation with business operations in the State of New York consisting of a health care network that includes ownership, operation, control, management, direction and supervision of five teaching hospitals, ten community hospitals, three specialty care hospitals, the Hofstra Northwell School of Medicine, a medical research institute, outpatient health care facilities,

⁶ This party is also variously referred to as “LENOX HILL”, “L.H.H.”, and the “hospital” *infra*.

rehabilitation facilities, skilled nursing facilities, a home care network, a hospice network and physician medical groups.

40. That at all times hereinafter mentioned, defendant NORTHWELL HEALTH, INC., was and is a corporate health care network that owns, operates, controls, manages, directs and supervises defendant LENOX HILL HOSPITAL.

41. That at all times hereinafter mentioned, defendant NORTHWELL HEALTH, INC., was and is a corporate health care network that controls all structural, financial and management decisions of defendant LENOX HILL HOSPITAL.

42. That at all times hereinafter mentioned, defendant NORTHWELL HEALTH, INC.,⁷ was and is a corporate health care network that is the corporate alter ego of defendant LENOX HILL HOSPITAL.

43. That at all times hereinafter mentioned, defendants DAVID B. SAMADI, M.D., DAVID B. SAMADI, M.D., P.C., LENOX HILL HOSPITAL, and NORTHWELL HEALTH, INC., offered professional medical services, including medical, surgical and urology care and treatment to the public and patients in general, including STEPHEN MARKELSON and PETER NADLER.

JURISDICTION

44. That the jurisdiction of this Court is premised upon 28 U.S.C. §1331 in that this is a civil action involving violations of the laws of the United States, i.e., 31 U.S.C. §§ 3729-3733, et seq., (the “False Claims Act”) and invokes subject matter jurisdiction.

⁷ This party is also variously referred to as “NORTHWELL HEALTH”, “NORTHWELL”, and the “hospital’s owner” or “hospital’s operator” infra.

VENUE

45. That the venue of this action is premised upon the violations of federal law and fraudulent conduct, acts, omissions, and transactions that form the basis of the plaintiff-relators' Complaint occurring in the City of New York, County of New York, and State of New York, the defendants also maintain business operations, places of business, and engage in business transactions in this venue, and defendants SAMADI, SAMADI, P.C., and LENOX HILL HOSPITAL maintain principal executive offices in this venue.

JURY DEMAND

46. That plaintiff-relators demand trial by jury of all issues presented in this action that are triable as of right by a jury pursuant to *Fed. R. Civ. P. 38 (a)*.

SYNOPSIS

47. This action is brought by the relators on behalf of themselves and the UNITED STATES OF AMERICA for violations of 31 U.S.C. §§ 3729-3733, i.e., the False Claims Act, related to fraudulent Medicare billing by defendants DAVID B. SAMADI, M.D., DAVID B. SAMADI, M.D., P.C., LENOX HILL HOSPITAL and NORTHWELL HEALTH, INC.

48. The defendants' fraudulent Medicare billing scheme commenced after NORTHWELL HEALTH and LENOX HILL HOSPITAL hired SAMADI as the hospital's chairman of the urology department.

49. The fraud scheme was perpetrated during the period 2013 – 2016, and continues to the present in varied permutations.
50. During this period of time, defendants DAVID B. SAMADI, M.D., DAVID B. SAMADI, M.D., P.C., LENOX HILL HOSPITAL and NORTHWELL HEALTH, INC., perpetrated an extensive pattern of fraudulent conduct in which they submitted false claims to Medicare (and also Medicaid and private commercial health insurers) for payments related to (1) “simultaneous” or “concurrent” urologic surgeries by unsupervised second and third year residents, (2) medically unjustifiable general anesthesia services and excessively prolonged general anesthesia services, (3) medical treatment undertaken without proper informed consents from the patients, and (4) medical treatment documented with false and/or misleading records.
51. The claims were submitted to Medicare (and also Medicaid and private commercial health insurers) and payments or reimbursements were received by the defendants with full knowledge and awareness that such claims contained false statements, misrepresentations, misleading assertions, omissions, and “half-truths” that concealed material violations of Medicare statutory, regulatory and/or contractual requirements.
52. Defendants’ own urologic surgery databases (encompassing the period 2004 – 2016), O.R. schedules, and anesthesia records, among other records and databases, corroborate the foregoing elements of the fraud scheme. (See, Exhibit A, LHH Urologic Surgery Database, 2004 – 2013; Exhibit B, LHH Urologic Surgery Database [Samadi], 2013 – 2016; Exhibit C, LHH Urology Department

O.R. Schedule, 2015; Exhibit D, LHH Urology Department O.R. Schedule, 2017; Exhibit E, LHH Anesthesia Records, March 4, 2015.⁸)

53. There were and are four (4) elements to the unlawful scheme that resulted in the submission of fraudulent claims to Medicare for payment by defendants DAVID B. SAMADI, M.D., DAVID B. SAMADI, M.D., P.C., LENOX HILL HOSPITAL and NORTHWELL HEALTH, INC.

54. Those elements can be summarized as follows:

55. Defendants DAVID B. SAMADI, M.D., DAVID B. SAMADI, M.D., P.C., LENOX HILL HOSPITAL and NORTHWELL HEALTH, INC., fraudulently conspired to bill Medicare, Medicaid and private commercial health insurers for more than 1,000 urologic surgeries performed entirely by unsupervised second and third year residents in O.R. 21 in which SAMADI or a qualified attending urologist was not present for the requisite “critical or key portions” of the surgery or the “entire viewing” during endoscopic / laparoscopic surgery and was not immediately available to return to the O.R. if needed by the resident. During the surgeries performed by unsupervised residents in O.R. 21, SAMADI was simultaneously or concurrently performing robotic assisted laparoscopic prostatectomy surgeries (i.e., RALPs) in O.R. 25. This pattern of conduct, to the extent it involved treatment for Medicare beneficiaries, was clearly in violation of Medicare regulations.⁹

⁸ Exhibits A – E annexed to this Complaint were obtained by plaintiff-relators’ attorneys with the names, dates of birth and residence addresses already redacted from these records; therefore, the materials were received in a format that does not breach patient confidentiality.

⁹ See, 42 C.F.R. 415.170; 42 C.F.R. 415.172; 42 C.F.R. 415.172(a); 42 C.F.R. 172(a)(1); CMS 2011 Medicare Claims Processing Manual, 100.1.2-A, Surgical Procedures; CMS 2011 Medicare Claims Processing Manual, 100.1.2-A.5, Surgical Procedures; CMS 2011 Medicare Claims Processing Manual, 100.1.8 (B) (Physician Billing in the Teaching Setting); Medicare Carriers Manual, Part 3, CMS Pub. 14-3

56. Defendants DAVID B. SAMADI, M.D., DAVID B. SAMADI, M.D., P.C., LENOX HILL HOSPITAL and NORTHWELL HEALTH, INC., fraudulently conspired to bill Medicare, Medicaid and private commercial health insurers for general anesthesia services that were medically unjustifiable and excessively prolonged; SAMADI ordered general anesthesia for more than 1,000 surgeries in O.R. 21 so that the patients would be unaware that their surgery was being performed by a urology resident without supervision and not SAMADI. The use of general anesthesia for the surgeries performed by residents in O.R. 21 was not medically necessary or indicated under standards of proper urology practice since the surgical procedures are customarily and safely performed under spinal or epidural anesthesia with sedation. This pattern of conduct, to the extent it involved treatment for Medicare beneficiaries, was clearly in violation of Medicare regulations.¹⁰

57. Defendants DAVID B. SAMADI, M.D., DAVID B. SAMADI, M.D., P.C., LENOX HILL HOSPITAL and NORTHWELL HEALTH, INC., fraudulently conspired to bill Medicare, Medicaid and private commercial health insurers for surgeries, anesthesia services and related medical treatment that lacked a proper informed consent. The patients undergoing the urological surgeries in O.R. 21

(Rev. 1780); 42 C.F.R. 415.172 et seq.; Fed. Reg. 63124-01, 1995 WL 723389 (F.R.); U.S. Senate Finance Committee Report, Appendix, "Concurrent and Overlapping Surgeries: Additional Measures Warranted", p. 19, December 6, 2016.

¹⁰ See, 42 C.F.R. §482.13 (Condition of participation: Patient's rights); 42 C.F.R. § 482.13(b)(1)-(2); 42 C.F.R. § 482.13(c)(2); 42 C.F.R. § 482.51(b)(2) (Condition of participation: Surgical services); 42 C.F.R. § 482.24(c)(2)(B)(v) (Condition of participation: Medical record services); CMS State Operations Manual, Regulations and Interpretive Guidelines for Hospitals (Rev. 151; 11-20-15); CMS 2007 Hospital Interpretive Guidelines for Informed Consent; AMA Council on Ethical and Judicial Affairs Opinion E-8.16, "Substitution of Surgeon Without Patient's Knowledge or Consent"; Ghost Surgery: The Ethical and Legal Implications of Who Does the Operation, Kocher, MS, J Bone Joint Surg Am, 84: 148-150 (2002); American Urological Association Code of Ethics (2014).

were all defendant SAMADI's patients who were defrauded into believing that SAMADI would be performing the planned surgery on them. SAMADI had specifically advised these patients that he would be personally performing their surgeries. Contrary to these fraudulent representations, approximately one thousand or more of SAMADI's patients underwent surgery by unsupervised second and third year urology residents and were placed under general anesthesia without a proper informed consent. This pattern of conduct, to the extent it involved treatment for Medicare beneficiaries, was also clearly in violation of Medicare regulations.¹¹

58. Defendants DAVID B. SAMADI, M.D., DAVID B. SAMADI, M.D., P.C., LENOX HILL HOSPITAL and NORTHWELL HEALTH, INC., fraudulently conspired to bill Medicare (and also Medicaid and private commercial health insurers) for surgeries, anesthesia services and related medical treatment that involved the preparation of fraudulent medical records (e.g., operative reports, anesthesia records, operative case records, etc.) that falsely indicated that SAMADI had either performed the surgery, was present for "the critical or key portions of the surgery", and/or was present for the "entire viewing" portion of the endoscopic / laparoscopic surgery for the operations in O.R. 21 that had been performed by the unsupervised residents. This pattern of conduct, to the extent it involved treatment for Medicare beneficiaries, was also clearly in violation of Medicare regulations.¹²

¹¹ See, 42 C.F.R. 415.172(b); 130 CMR 450.275(D) (Covered Services).

¹² See, 31 U.S.C.A. § 3729(a)(1)(A), § 3729 (b)(4).

59. Plaintiff-relators' are the "original source" of the information and evidence set forth in this Complaint and its annexed exhibits pertaining to the defendants' pattern of fraudulent conduct and consequent violations of Medicare regulations pursuant to 31 U.S.C. § 3730(e)(4)(B); the undersigned counsel's investigation revealed the evidentiary sources corroborating the defendants' fraud scheme during April – November 2016.

60. Defendants DAVID B. SAMADI, M.D., DAVID B. SAMADI, M.D., P.C., LENOX HILL HOSPITAL and NORTHWELL HEALTH, INC., submitted claims for payment to Medicare containing false statements, misrepresentations, misleading assertions, omissions and "half-truths" that concealed violations of Medicare statutory, regulatory, and/or contractual requirements with respect to the foregoing medical services provided to covered patients.

61. The defendants' false statements, misrepresentations, etc., were "false or fraudulent claims" pursuant to the U.S. False Claims Act (FCA).

62. The defendants' false statements, misrepresentations, etc., about compliance with Medicare statutory, regulatory, or contractual requirements were material to the federal government's payment decision; therefore, such false statements, misrepresentations, etc., were actionable under the U.S. False Claims Act (FCA).¹³

¹³ Plaintiff-relators are aware that some of Samadi's patients were covered under the Medicaid program; however, relators choose at this time to refrain from filing claims as relators on behalf of the State of New York under N.Y. State Finance Law §§ 187 – 194.

FACTS COMMON TO ALL COUNTS

63. This action is brought by the plaintiff-relators on behalf of the UNITED STATES OF AMERICA and themselves for violations of 31 U.S.C. §§ 3729-3733, i.e., the U.S. False Claims Act, related to fraudulent Medicare billing by defendants DAVID B. SAMADI, M.D., DAVID B. SAMADI, M.D., P.C., LENOX HILL HOSPITAL and NORTHWELL HEALTH, INC.
64. The defendants' fraudulent Medicare billing scheme commenced in July 2013 after NORTHWELL HEALTH and LENOX HILL HOSPITAL hired SAMADI as the hospital's chairman of the urology department.
65. The defendants' fraud scheme was perpetrated during the period 2013 – 2016 and has continued to the present in partially varied permutations.
66. The employment contract between NORTHWELL / LENOX HILL HOSPITAL and SAMADI includes incentive clauses related to surgical volume and revenue generation.

**Fraudulent Simultaneous Surgeries by Unsupervised
Second and Third Year Urology Residents in O.R. 21
While Samadi Engaged in RALP Surgeries in O.R. 25**

67. Defendants DAVID B. SAMADI, M.D., DAVID B. SAMADI, M.D., P.C., LENOX HILL HOSPITAL and NORTHWELL HEALTH, INC., without full and proper disclosure to patients, including STEPHEN MARKELSON and PETER NADLER, or proper informed consent from patients, simultaneously or concurrently booked, scheduled and performed two or more endoscopic / laparoscopic urological surgeries on different patients in two separate operating

rooms, O.R. 21 and O.R. 25, at LENOX HILL and used unsupervised second and third year urology residents to perform more than a thousand non-RALP surgeries.

68. The patients undergoing the endoscopic / laparoscopic urological surgeries in O.R. 25 and O.R. 21 were all defendant SAMADI's patients.

69. The patients were defrauded into believing that SAMADI would be performing the planned and scheduled surgeries since SAMADI had specifically advised these patients that he would be personally performing their surgeries.

70. Contrary to these fraudulent representations, approximately one thousand or more of SAMADI's patients underwent surgery by unsupervised urology residents.

71. The majority of the surgeries in O.R. 25 were robotic assisted laparoscopic prostatectomies (RALPs).

72. The majority of the surgeries in O.R. 21 were also endoscopic urological procedures including transurethral resections of the prostate (TURPs), cystoscopies, ureteroscopies, bladder biopsies, and ureteroscopic lithotripsies.

73. The RALPs in O.R. 25 were performed by defendant SAMADI.

74. Unsupervised second and third year urology residents performed the endoscopic / laparoscopic urological surgeries on SAMADI's patients in O.R. 21 (e.g., TURPs, cystoscopies, ureteroscopies, etc.).

75. The urological surgeries in O.R. 21 by the unsupervised residents were all performed under general anesthesia at SAMADI's instructions.

76. The use of general anesthesia for the surgeries in O.R. 21 was not medically necessary or indicated under standards of proper urology practice since such

surgical procedures are customarily and safely performed under spinal or epidural anesthesia with sedation.

77. Defendant SAMADI ordered general anesthesia for the patients in O.R. 21 so that they would be unaware that their surgery was being performed by a urology resident without supervision.

78. The use of general anesthesia on patients in O.R. 21 meant that the unwitting patient faced unnecessary risks to life and health by being fully anesthetized – unconscious, paralyzed, intubated, dependent on a ventilator to breathe – without medical justification.

79. The general anesthesia used on SAMADI's patients was also excessively prolonged.

80. Defendant SAMADI was never present during the “critical portions of the surgery” and/or the “entire viewing” portion of the endoscopic / laparoscopic surgeries by the residents in O.R. 21.

81. Defendant SAMADI was never immediately available to assist the urology resident performing surgery in O.R. 21 since he was simultaneously or concurrently engaged in performing a RALP in O.R. 25.

82. Defendant SAMADI also never arranged for another qualified urologic surgeon to be immediately available to assist the urology resident performing surgery in O.R. 21 should the need arise.

83. Moreover, defendant SAMADI was not always present for the “entire viewing” portion of the surgery for the RALPs in O.R. 25; episodically leaving this

operating room while unguided surgical instruments were still inside the abdomen of the patient.

84. Defendant SAMADI and the employees and/or agents of defendants LENOX HILL HOSPITAL and NORTHWELL HEALTH prepared fraudulent medical records falsely indicating that SAMADI had either performed the surgery, was present for the “critical or key portions of the surgery” and/or was present for the “entire viewing” portion of the endoscopic / laparoscopic surgery for the non-RALP operations in O.R. 21 that had been performed by the unsupervised residents.

85. Pursuant to the terms of SAMADI’s employment contract with NORTHWELL and LENOX HILL, the personnel working in SAMADI’s private medical office were permitted to remain the employees of SAMADI, P.C., and SAMADI was permitted to maintain the lease on the office premises; however, NORTHWELL employed the surgical schedulers and medical biller for SAMADI’s medical practice.

86. Defendants LENOX HILL HOSPITAL and NORTHWELL HEALTH employed the O.R. schedulers, O.R. administrators, O.R. supervisory staff, medical billers, and O.R. personnel (e.g., O.R. nurses, anesthesiologists, residents, etc.) for the surgeries and related medical services performed at the hospital in connection with SAMADI’s fraudulent simultaneous surgery scheme.

87. Defendants LENOX HILL HOSPITAL and NORTHWELL HEALTH, INC., through their executives (e.g., Michael Dowling, CEO, Gus Costalas, CFO, Dennis Connors, Executive Director), administrators (Louis Kavoussi, M.D., Northwell

urology chairman), medical director, chief medical officer (Jill Kalman, M.D.), chief of surgery / director of the operating room committee (Gary Giangola, M.D.), O.R. schedulers (e.g., Jennifer Whiffen, R.N.), O.R. administrators (e.g., Eleonora Shapiro, R.N.), O.R. supervisory staff, surgical bookers, medical billers, urology residents (Leonard Glickman, M.D., Billy Cordon-Galiano, M.D., a/k/a Billy Cordon, M.D., Nitin Sharma, M.D., Yaniv Larish, M.D., Johnson Tsui, M.D., Shawn Mendonca, M.D., Joseph Sarcona, M.D., Daniel Nassau, M.D.), O.R. nursing staff, anesthesiologists, CRNAs, and other attending urologists, were and are fully knowledgeable and aware of SAMADI's above referenced simultaneous surgery / concurrent surgery practices.

88. By their actions, LENOX HILL HOSPITAL, NORTHWELL HEALTH and their executives, administrators, medical director, chief medical officer, chief of surgery / director of the operating room committee, and O.R. administrators authorized, approved, permitted, allowed, ratified, enabled, equipped, supported, assisted, encouraged, and promoted SAMADI's above referenced fraudulent simultaneous surgery scheme.

89. The above referenced pattern of fraudulent conduct by the defendants violates Medicare regulations established by the federal government as a material condition of payment for claims submitted under this government program.

90. Defendants DAVID B. SAMADI, M.D., DAVID B. SAMADI, M.D., P.C., LENOX HILL HOSPITAL and NORTHWELL HEALTH, INC., intentionally, knowingly and purposefully submitted fraudulent billing or "claims" with material false statements, misrepresentations, misleading assertions and omissions

to the Medicare program related to the simultaneous surgery scheme in O.R. 21 and O.R. 25, to the extent it involved treatment for Medicare beneficiaries, involving the use of unsupervised second and third year urology residents.

91. Defendants DAVID B. SAMADI, M.D., DAVID B. SAMADI, M.D., P.C., LENOX HILL HOSPITAL and NORTHWELL HEALTH, INC., conspired to intentionally, knowingly and purposefully perpetrate the foregoing simultaneous surgery scheme in violation of Medicare regulations and submit fraudulent Medicare billing.

92. As a result of the foregoing pattern of fraudulent conduct, defendants DAVID B. SAMADI, M.D., DAVID B. SAMADI, M.D., P.C., LENOX HILL HOSPITAL and NORTHWELL HEALTH, INC., improperly received substantial payments from the Medicare program.

93. The pattern of fraudulent conduct related to the above referenced simultaneous surgery scheme in O.R. 21 and O.R. 25 and consequent violations of the Medicare regulations by defendants DAVID B. SAMADI, M.D., DAVID B. SAMADI, M.D., P.C., LENOX HILL HOSPITAL and NORTHWELL HEALTH, INC., was undertaken knowingly, intentionally, and purposefully; i.e., the defendants acted with knowledge and awareness of the falsity of the statements made in connection with the billing for medical services, the violations of Medicare regulations and the materiality of the false statements that would have otherwise led to denials of payment on the claims by the federal government if such claims were truthful and accurate.

94. The foregoing fraud scheme perpetrated by defendants SAMADI, M.D., SAMADI, P.C., LENOX HILL and NORTHWELL further worked as follows:
95. The fraud scheme perpetrated by the defendants was systematic and pervasive and encompassed the urology department and other departments performing surgeries and operative procedures at LHH and other NORTHWELL hospitals.
96. The fraud scheme perpetrated by the defendants occurred during the period 2013 – 2016 and continued in varied permutations until the present.
97. The fraud scheme perpetrated by the defendants encompassed more than 2,250 urological surgeries and operative procedures on SAMADI's patients at LHH during the period 2013 - 2016.
98. SAMADI engaged in "double-booking" or "concurrently" and "simultaneously" scheduling two O.R.'s – usually O.R. 21 and O.R. 25 – for multiple surgeries and operative procedures on his patients approximately 2 – 3 days per week.
99. SAMADI would schedule robotic assisted laparoscopic prostatectomy surgeries (RALPs) on his patients in O.R. 25.
100. SAMADI would schedule all other urologic surgeries and operative procedures, (e.g., TURPs, cystoscopies, ureteroscopies, bladder biopsies, and ureteroscopic lithotripsies, etc.) in O.R. 21 and occasionally other O.R.'s as well.
101. SAMADI would personally perform all RALPs in O.R. 25 on his patients.
102. Unsupervised second and third year urology residents (e.g., Dr. Glickman, Dr. Cordon, Dr. Sharma, Dr. Larish, Dr. Tsui, Dr. Mendonca, Dr. Sarcona, Dr. Nassau) would perform the primarily endoscopic urology procedures (e.g.,

TURPs, cystoscopies, ureteroscopies, bladder biopsies, and ureteroscopic lithotripsies, etc.) in O.R. 21.

103. On occasion, SAMADI would temporarily abandon patients during the RALPs in O.R. 25 to walk over to O.R. 21 to perform a mandated “timeout” for the urologic surgery that was to be performed on his patient by the resident.

104. SAMADI frequently left the RALP in O.R. 25 with unguided surgical instruments inside the patients’ abdomens.

105. Once the “timeout” was performed in O.R. 21, SAMADI would leave the resident to perform the surgery on the patient without any supervision and return to O.R. 25 to resume the RALP on his other patient.

106. All of the “concurrent” and “simultaneous” urologic surgeries and operative procedures were performed on SAMADI’s patients in O.R. 21 by unsupervised urology residents.

107. Those urology residents participating or involved in the performance of unsupervised urological surgeries on SAMADI’s patients in O.R. 21 during 2013 – 2016 and continuing to the present are identified as Leonard Glickman, M.D., Billy H. Cordon-Galiano, M.D., a.k.a., Billy Cordon, M.D., Nitin Sharma, M.D., Yaniv Larish, M.D., Johnson Tsui, M.D., Shawn Mendonca, M.D., Joseph Sarcona, M.D., and Daniel Nassau, M.D.

108. The surgeries and operative procedures in O.R. 21 – almost entirely consisting of endoscopic surgical procedures (e.g., TURPs, cystoscopies, ureteroscopies, bladder biopsies, ureteroscopic lithotripsies, etc.) – were all performed by the above identified urology residents without supervision.

109. According to the investigation by plaintiff-relators' attorneys, Dr. Glickman, Dr. Cordon, Dr. Sharma, Dr. Larish, Dr. Tsui, Dr. Mendonca, Dr. Sarcona, Dr. Nassau, each performed as many as 200 – 250 unsupervised non-RALP urologic surgeries on SAMADI's patients during their employment as second and third year residents; most of these surgeries were endoscopic surgical procedures (e.g., TURPs, cystoscopies, ureteroscopies, bladder biopsies, ureteroscopic lithotripsies, etc.) in O.R. 21.
110. SAMADI was never present for the "entire viewing" during the endoscopic surgeries and operative procedures performed by unsupervised residents in O.R. 21.
111. SAMADI was never present for the "critical or key portions" of the surgeries and operative procedures in O.R. 21 performed by unsupervised residents.
112. SAMADI falsely represented to his patients that he would be personally performing all the urologic surgeries and operative procedures on his patients, including RALPs, TURPs, cystoscopies, ureteroscopies, bladder biopsies, and ureteroscopic lithotripsies.
113. SAMADI made fraudulent misrepresentations to his patients that concealed the actual circumstances of the "concurrent" and "simultaneous" urologic surgeries and operative procedures performed on his patients.
114. SAMADI fraudulently misled and deceived his patients by failing to inform and advise them of the truth that the "concurrent" and "simultaneous"

urologic surgeries and operative procedures would be performed on them by residents and instead led them to believe that he was to perform their surgeries.

115. SAMADI fraudulently misled and deceived his patients by failing to inform them of the truth that the “concurrent” and “simultaneous” urologic surgeries and operative procedures would be performed on them by unsupervised residents.

116. SAMADI fraudulently misled and deceived his patients by failing to inform and advise them of the truth that the “concurrent” and “simultaneous” non-RALP urologic surgeries and operative procedures would be performed by residents while he was engaged in performing RALPs on other patients in O.R. 25.

117. SAMADI unnecessarily subjected patients undergoing non-RALP surgeries and operative procedures (e.g., TURPs, cystoscopies, ureteroscopies, bladder biopsies, ureteroscopic lithotripsies) by the unsupervised residents to general anesthesia instead of the usual and customary epidural or spinal anesthesia with sedation.

118. SAMADI ordered his patients to be placed under general anesthesia for the non-RALP surgeries and operative procedures by the residents in O.R. 21 so that they would not know that unsupervised residents were performing the surgeries.

119. SAMADI ordered his patients to be placed under general anesthesia for the non-RALP surgeries and operative procedures by the residents in O.R. 21 so

that they would not know that he was absent from the operating room for their surgeries.

120. SAMADI, LHH and NORTHWELL falsely represented to the patients that SAMADI would be personally performing all the urologic surgeries and operative procedures on patients, including RALPs, TURPs, cystoscopies, ureteroscopies, bladder biopsies, and ureteroscopic lithotripsies, on the consent forms given to patients prior to the surgery.

121. SAMADI, LHH and NORTHWELL fraudulently concealed the truthful, honest and accurate circumstances of the “concurrent” and “simultaneous” urologic surgeries and operative procedures performed on them through the consent form.

122. SAMADI, LHH and NORTHWELL fraudulently misled and deceived patients by failing to inform and advise them of the truth that the “concurrent” and “simultaneous” non-RALP urologic surgeries and operative procedures would be performed by unsupervised residents in O.R. 21 while SAMADI performed RALPs on different patients in O.R. 25.

123. LHH and NORTHWELL employed the urology residents performing the unsupervised “simultaneous” / “concurrent” urologic surgeries in O.R. 21 and/or participating or involved in those surgeries.

124. LHH and NORTHWELL are vicariously liable under respondeat superior and agency principles for the foregoing actions, omissions and conduct of SAMADI in relation to the foregoing fraud scheme.

125. LHH and NORTHWELL are vicariously liable under respondeat superior and agency principles for the foregoing actions, omissions and conduct of Dowling, Costalas, Kavoussi, Kalman, Giangola, Whiffen, Shapiro, and others in relation to the foregoing fraud scheme.

126. LHH and NORTHWELL are vicariously liable for the foregoing actions, omissions and conduct of Glickman, Cordon-Galiano, Sharma, Larish, Tsui, Mendonca, Sarcona, Nassau and residents, physician assistants, O.R. nurses, and anesthesiologists involved and participating in the activities serving as the basis of the foregoing fraud scheme to the extent that such activities caused injury or loss to patients or violated the informed consent rights of patients.

127. Glickman, Cordon-Galiano, Sharma, Larish, Tsui, Mendonca, Sarcona, Nassau and other residents, physician assistants, O.R. nurses, and anesthesiologists performed, participated in and/or were involved in the activities serving as the basis of the foregoing fraud scheme in accordance with the orders, directives and instructions given to them by SAMADI and other superiors, supervisors and managers.

128. Glickman, Cordon-Galiano, Sharma, Larish, Tsui, Mendonca, Sarcona, Nassau and other residents, physician assistants, O.R. nurses, and anesthesiologists, to the extent that they followed and complied with the above described orders, directives and instructions given to them by SAMADI and other superiors, supervisors and managers, did so out of fear that their employment with LENOX HILL and NORTHWELL would be terminated or otherwise be subject

to other forms of retaliation if they objected to the same or refused to comply with the same.

129. SAMADI, LHH and NORTHWELL further defrauded patients covered by Medicare, Medicaid and/or private health insurers by billing them excess amounts for surgeon's fees, co-payments and account balances related to the "concurrent" and "simultaneous" non-RALP urologic surgeries and operative procedures performed by unsupervised residents in O.R. 21.

130. SAMADI, LHH and NORTHWELL defrauded patients covered by Medicare, Medicaid and/or private health insurers by billing them excess amounts for co-payments and account balances related to medically unjustifiable and unnecessary general anesthesia services and excessively prolonged general anesthesia services related to the "concurrent" and "simultaneous" non-RALP urologic surgeries and operative procedures performed by unsupervised residents in O.R. 21.

131. SAMADI, LHH and NORTHWELL defrauded patients covered by Medicare, Medicaid and/or private health insurers by billing them excess amounts for co-payments and account balances for medical treatment that lacked a legal and proper informed consent related to the "concurrent" and "simultaneous" non-RALP urologic surgeries and operative procedures performed by unsupervised residents in O.R. 21.

132. SAMADI, LHH and NORTHWELL, acting in concert, conspired to conceive, create, develop, formulate, implement and perpetrate the foregoing pervasive and systemic fraud scheme for the express motive and purpose of

markedly increasing and inflating the volumes for urologic surgeries, inpatient admissions, anesthesia services and medical services with the corresponding result of markedly increasing and inflating billing revenue, health system profits and physician income and compensation.

133. As a result of the concealed and nonconsensual “double-booking”, “concurrent surgeries” and “simultaneous surgeries” practices by SAMADI, LHH and NORTHWELL, all of SAMADI’s patients undergoing such surgeries and operative procedures in O.R. 21 and O.R. 25 were victims of fraud; fraudulent misrepresentation; a pervasive and systematic fraud scheme; deceptive medical practices; non-consensual medical treatment; departures from standards of proper surgical practices; and violations of medical ethics.

The Northwell / LHH Urologic Surgery Database

134. During 2016, the investigation undertaken by plaintiff-relators’ attorneys revealed that defendants LENOX HILL and NORTHWELL maintained surgery databases that contained detailed information on every surgery and operation performed by the LHH department of urology starting in 2004 and continuing through the present.
135. During 2016, the investigation undertaken by plaintiff-relators’ attorneys resulted in the disclosure of representative portions of the foregoing surgery databases through receipt of a copy of the same.
136. Analysis of the LENOX HILL / NORTHWELL urologic surgery databases demonstrates and corroborates the existence of the “double-booking”,

“concurrent surgeries” and “simultaneous surgeries” fraud scheme perpetrated by the defendants during 2013 - 2016.

137. The LENOX HILL / NORTHWELL urologic surgery databases are annexed in printed format to this Complaint as Exhibit A, LHH Urologic Surgery Database, 2004 – 2013, and Exhibit B, LHH Urologic Surgery Database [Samadi], 2013 – 2016. (See, Exhibit A, LHH Urologic Surgery Database, 2004 – 2013; Exhibit B, LHH Urologic Surgery Database [Samadi], 2013 – 2016.)

138. Analysis of the LENOX HILL / NORTHWELL urologic surgery databases demonstrate that, during the period 2004 – June 2013, there were no “concurrent”, “simultaneous” or “double booked” urologic surgeries at LHH performed on any of the patients by the hospital’s attending urologists (SAMADI was not affiliated with LHH or NORTHWELL prior to July 2013). (See, Exhibit A, LHH Urologic Surgery Database, 2004 – 2013.)

139. Analysis of the LENOX HILL / NORTHWELL urologic surgery databases demonstrates that, during the period July 2013 – August 2016, there were numerous “concurrent”, “simultaneous” or “double booked” urologic surgeries at LHH performed only on SAMADI’s patients. (See, Exhibit B, LHH Urologic Surgery Database [Samadi], 2013 – 2016.)

140. During the period July 1, 2013 – August 31, 2016, there were 2,182 urologic surgeries on SAMADI’s patients at LHH.

141. During the period July 1, 2013 – August 31, 2016, there were 1,207 out of the 2,182 total urologic surgeries (i.e., approx. 55%) on SAMADI’s patients at LHH that constituted “simultaneous” or “concurrent” surgeries because the time

of the operative procedure in O.R. 21 was entirely or mostly encompassed by the operative procedure in O.R. 25.

142. During the period July 1, 2013 – August 31, 2016, there were 424 out of the 2,182 urologic surgeries (i.e., approx. 20%) on SAMADI’s patients at LHH that constituted “simultaneous” or “concurrent” surgeries in which the time of the operative procedure in O.R. 21 was entirely or totally encompassed by the operative procedure in O.R. 25; i.e., the surgery in O.R. 25 started before the start of the surgery in O.R. 21 and the surgery in O.R. 25 ended after the end of the surgery in O.R. 21.

143. During the period July 1, 2013 – August 31, 2016, there were 783 out of the 2,182 urologic surgeries (i.e., approx. 36%) on SAMADI’s patients at LHH that constituted “simultaneous” or “concurrent” surgeries because the time of the operative procedure in O.R. 21 was mostly or significantly encompassed by the operative procedure in O.R. 25; i.e., the start and end times of the surgeries in O.R. 25 and O.R. 21 were contemporaneous or synchronous for all but a short duration of time.

144. During the period July 1, 2013 – August 31, 2016, there were 1,530 out of the 2,182 urologic surgeries (i.e., approx. 70%) on SAMADI’s patients at LHH that constituted “overlapping” surgeries, i.e., the time of the operative procedure in O.R. 21 was encompassed to some degree by the operative procedure in O.R. 25.

145. An example illustrating the defendants’ foregoing fraudulent “simultaneous” / “concurrent” surgery scheme is the date of March 5, 2014, when

eleven (11) surgeries were performed on SAMADI's patients at LENOX HILL; 10 out of the 11 surgeries were "simultaneous" / "concurrent".

146. On March 5, 2014, SAMADI performed five (5) RALPs in O.R. 25 and the residents performed six (6) non-RALP urologic surgeries on his patients in O.R. 21.

147. The RALPs in O.R. 25 encompassed the following times: 6:40 – 8:38, 9:00 – 11:06, 11:38 – 13:50, 14:22 – 14:32, 14:55 – 15:22, and the non-RALPs in O.R. 21 (all endoscopic urologic procedures) encompassed the following times: 7:20 – 8:30, 8:55 – 11:40, 12:13 – 12:59, 13:30 – 14:35, 14:50 – 15:33, 16:08 – 17:45.

148. Medicare covered eight (8) out of the eleven (11) SAMADI patients undergoing surgery on March 5, 2014; the other three (3) were private commercial insurance.

The Northwell / LHH O.R. Schedules

149. During 2016, the investigation undertaken by plaintiff-relators' attorneys revealed that defendants LENOX HILL and NORTHWELL issued a daily O.R. schedule for the hospital's urology department that contained detailed information on every urologic surgery performed at the hospital.

150. During 2016, the investigation undertaken by plaintiff-relators' attorneys resulted in the disclosure of the foregoing daily O.R. schedules from 2015 through receipt of a copy of the same.

151. Analysis of the LENOX HILL / NORTHWELL daily O.R. schedules demonstrates and corroborates the existence of the “double-booking”, “concurrent surgeries” and “simultaneous surgeries” fraud scheme perpetrated by SAMADI, LENOX HILL and NORTHWELL during August – October 2015.
152. The LENOX HILL / NORTHWELL daily O.R. schedules during August – October 2015 are annexed to this Complaint as Exhibit C, LHH Urology Department O.R. Schedule, 2015. (See, Exhibit C, LHH Urology Department O.R. Schedule, 2015.)
153. During 2017, the continued investigation undertaken by plaintiff-relators’ attorneys resulted in the disclosure of additional daily O.R. schedules from 2017 through receipt of a copy of the same.
154. Analysis of the LENOX HILL / NORTHWELL daily O.R. schedules obtained in 2017 demonstrates and corroborates the continued existence of the “double-booking”, “concurrent surgeries” and “simultaneous surgeries” fraud scheme perpetrated by SAMADI, LENOX HILL and NORTHWELL during February – March 2017.
155. The LENOX HILL / NORTHWELL daily O.R. schedules during February – March 2017 are annexed to this Complaint as Exhibit D, LHH Urology Department O.R. Schedule, 2017. (See, Exhibit D, LHH Urology Department O.R. Schedule, 2017.)

The Northwell / LHH Anesthesia Records

156. During 2016, the investigation undertaken by plaintiff-relators' attorneys revealed that defendant LENOX HILL / NORTHWELL maintained anesthesia records for the surgeries on SAMADI's patients; these anesthesia records contain information relevant to this matter.
157. During 2016, the investigation undertaken by plaintiff-relators' attorneys resulted in the disclosure of anesthesia records from May 4, 2015, through receipt of a copy of the same.
158. Analysis of the LENOX HILL / NORTHWELL anesthesia records demonstrates and corroborates the existence of the "double-booking", "concurrent surgeries" and "simultaneous surgeries" fraud scheme perpetrated by SAMADI, LENOX HILL and NORTHWELL on May 4, 2015.
159. The LENOX HILL / NORTHWELL anesthesia records for May 4, 2015, are annexed to this Complaint as Exhibit E. (See, Exhibit E, LHH Anesthesia Records, March 4, 2015.)
160. The LENOX HILL / NORTHWELL anesthesia records for May 4, 2015, read in conjunction with the foregoing LHH urologic surgery database, demonstrates and corroborates that three (3) non-RALP endoscopic urologic surgeries were performed on SAMADI's patients in O.R.'s 21 and 24 while four (4) RALPs were "simultaneously"/"concurrently" performed in O.R. 25 on SAMADI's patients.
161. The LENOX HILL / NORTHWELL anesthesia records, read in conjunction with the foregoing LHH urologic surgery database, demonstrates and

corroborates that the three (3) non-RALP endoscopic urologic surgeries performed on SAMADI's patients in O.R.'s 21 and 24 occurred during the times 09:00 – 10:32, 10:52 – 12:30, 16:45 – 18:10, while the four (4) RALPs performed in O.R. 25 on SAMADI's patients occurred during the times 06:50 – 09:15, 09:35 – 12:35, 12:55 – 15:35, 15:50 – 18:30.

162. Thus, on May 4, 2015, 2 out of the 3 non-RALP surgeries on SAMADI's patients were entirely or completely encompassed by 2 of the "simultaneous"/"concurrent" RALPs on SAMADI's patients and 1 non-RALP surgery was mostly encompassed by 1 "simultaneous"/"concurrent" RALP.

**"Simultaneous Surgeries" were Banned for Decades
in the LHH Urology Department Pre-July 2013**

163. During the period 2004 – June 2013, three attending urologists served in the position of chairman of the urology department at LHH.

164. John A. Fracchia, M.D., served as chairman of urology at the hospital for twenty-five (25) years during the period 1983 – 2008; Dr. Fracchia remains affiliated as an attending urologist at LHH.

165. Dr. Fracchia's tenure as LHH's urology department chairman spanned a portion of the time frame covered during the period 2004 – June 2013 that is the pre-Samadi portion of Exhibit A, LHH Urologic Surgery Database, 2004 – 2013.

166. Michael S. Brodherson, M.D., and R. Ernest Sosa, M.D., briefly served as interim chairman of the LHH urology department.

167. Dr. Brodherson and Dr. Sosa remain affiliated as attending urologists at LHH.

168. In July 2013, defendant SAMADI assumed the positions of chairman of the urology department and director of the urology residency program.

169. According to Dr. Fracchia, he always refused as chairman to allow “simultaneous surgery”, “concurrent surgery” or “double booking” practices by doctors in the LHH urology department.¹⁴

170. The urologic surgery databases corroborate Dr. Fracchia’s simultaneous surgery ban during 2004 – 2008. (See, Exhibit A, LHH Urologic Surgery Database, 2004 – 2013.)

171. Apparently, Dr. Brodherson and Dr. Sosa always refused as interim chairmen to allow “simultaneous surgery”, “concurrent surgery” or “double booking” practices by doctors in the LHH urology department because the urologic surgery databases demonstrate the absence of simultaneous surgery practices at LHH during 2008 – June 2013. (See, Exhibit A, LHH Urologic Surgery Database, 2004 – 2013.)

172. The investigation undertaken by plaintiff-relators’ attorneys confirmed that “simultaneous surgery”, “concurrent surgery” or “double booking” practices by doctors in the LHH urology department was specifically banned starting, at least as far back as 1983, and continuing until SAMADI’s arrival at the hospital in July 2013.

173. According to Dr. Fracchia, SAMADI’s “simultaneous surgery”, “concurrent surgery” or “double booking” practices, as demonstrated by the LHH urologic surgery databases, are improper or, as he put it, “wrong”.¹⁵

¹⁴ (See, J. Saltzman & J. Abelson, Star Surgeon is Scrutinized on Concurrent Procedures, Boston Globe, March 12, 2017.)

174. Asked to comment upon SAMADI's "simultaneous surgery", "concurrent surgery" or "double booking" practices, as documented by LHH's daily O.R. schedule, Dr. Fracchia stated that it is "difficult" for him "to look at the operating room schedules on a daily basis, as the [hospital's] administration does, and not see that it's impossible for somebody to be at two places at the same time."¹⁶

175. The investigation undertaken by plaintiff-relators' attorneys revealed that the LHH urology department chairmen banned "simultaneous surgery" practices between 1983 and July 2013 for the purpose of adherence to standards of patient safety, surgical practice, medical ethics, residency training, and lawful billing practices.

176. The investigation undertaken by plaintiff-relators' attorneys revealed that, during the period that "simultaneous surgery" practices were banned in LHH's urology department, there was a robust, highly acclaimed, and fully ACGME accredited urology residency program in which residents were properly trained in urologic surgery by assisting in and actually performing operative procedures under the constant direct supervision of the department's chairmen and attending urologists.

177. Since SAMADI assumed the chairman and residency director positions in July 2013, the residents have been exploited by the defendants – SAMADI, LENOX HILL and NORTHWELL – to increase surgical volume, revenue, profits and physician compensation through performing unsupervised non-RALP

¹⁵ Id.

¹⁶ Id.

surgeries in the course of the fraudulent “simultaneous surgery” scheme at the expense of the quality of the urology residency training.

178. As a result of the foregoing exploitation of the residents by SAMADI, LENOX HILL and NORTHWELL, proper urologic residency training has been compromised.

179. Under SAMADI’s leadership as director, the accreditation of the LHH urology residency program was given a “warning” by the ACGME that was recently further downgraded to “probationary” status. (See, Exhibit F, ACGME Accreditation Status for Urology Residency Program at Northwell Lenox Hill Hospital.)

Northwell / Lenox Hill Publicly Admits that Samadi “Double-Books” Two Operating Rooms for Surgeries on his Patients

180. Defendants LENOX HILL and NORTHWELL do not deny SAMADI’s “double-booking”, “concurrent surgeries” and “simultaneous surgeries” but rather misrepresent and obfuscate about the improper, unethical and unlawful practices.

181. Barbara Osborn, a spokesperson for defendants LENOX HILL and NORTHWELL, has confirmed that SAMADI uses two operating rooms.¹⁷

182. Ms. Osborn falsely claimed that patients are informed that residents participate in surgeries “under supervision by a physician”; it is obvious for

¹⁷ (See, J. Saltzman & J. Abelson, Star Surgeon is Scrutinized on Concurrent Procedures, Boston Globe, March 12, 2017.)

reasons discussed infra that patients at LHH are not advised of this information in any way either before or after their surgeries.¹⁸

183. Ms. Osborn asserted that SAMADI “performs all of his robotic surgeries himself” but was notably silent on the issue of whether SAMADI performed the non-RALP urologic surgeries (e.g., TURPs, cystoscopies, ureteroscopies, bladder biopsies, ureteroscopic lithotripsies) that are actually performed by unsupervised urology residents in O.R. 21.

184. Ms. Osborn’s comments must be interpreted to give an implied acknowledgement that SAMADI does not perform all of the surgeries on his patients.

Analysis Summary of Northwell / LHH Urologic Surgery Database, O.R. Schedules & Anesthesia Records

185. The analysis of the LHH urologic surgery database, O.R. schedules and anesthesia records pertaining to SAMADI’s surgeries during 2013 – 2016 can be summarized as follows:

186. To the extent demonstrated and corroborated by the annexed exhibits and as described above, SAMADI’s surgeries did not merely overlap on their margins; they were performed at or about the same time, i.e., “simultaneously” or “concurrently”, making it impossible for defendant SAMADI to be physically present and ready to participate in the “critical or key portions” of a urologic surgery or present for the “entire viewing” during an endoscopic/laparoscopic surgery in O.R. 21 and O.R. 25.

¹⁸ (See, J. Saltzman & J. Abelson, Star Surgeon is Scrutinized on Concurrent Procedures, Boston Globe, March 12, 2017.)

187. To the extent demonstrated and corroborated by the foregoing annexed exhibits and as described above, the records and databases maintained by defendants LENOX HILL and NORTHWELL make it obvious and self evident that SAMADI was routinely performing “simultaneous surgeries” or “concurrent surgeries” in O.R. 21 and O.R. 25 on approximately a 2 – 3 day per week basis during the period 2013 - 2016.

188. The risks of surgery were compounded by the defendants’ failure to follow Medicare (and Medicaid) regulations, including those requiring immediate availability of SAMADI or another qualified teaching physician (i.e., an attending urologist), to go to the O.R. to assist the residents, if needed, in a non-RALP surgery.

189. The foregoing “double-booking”, “concurrent surgeries” and “simultaneous surgeries” practices of defendants SAMADI, LENOX HILL and NORTHWELL have caused harm to patients.

**Defendants’ Simultaneous Surgery Practices
Caused Physical Injury to Some Patients**

Simultaneous Surgery Harmed Patient Peter Nadler

190. Plaintiff-Relator NADLER was SAMADI’s patient starting in Spring 2015.

191. At the time, NADLER, then 66 years old, was a patient covered by Medicare and WATERS’ (his wife) private commercial health insurance policy through United Healthcare that was provided as an employment benefit.

192. NADLER was responsible for corresponding co-payments.

193. NADLER saw SAMADI's advertisements in the mass media and on the internet describing in extravagant terms that he was "the best in the world" among urologists and "NY's best prostate surgeon".
194. NADLER subsequently saw SAMADI for lower urinary tract symptoms (LUTS) including difficulties in voiding his bladder, weak urinary stream, incomplete bladder emptying, marked hesitancy, interruptions in urinary flow, low urinary outflow rate and volume, extreme nocturia (x 4-5 per night), pain and discomfort.
195. SAMADI diagnosed NADLER with BPH.
196. SAMADI recommended a TURP and scheduled NADLER for surgery at LHH on June 22, 2015.
197. SAMADI fraudulently led NADLER to believe that he would personally perform the TURP; he deceptively misrepresented to NADLER that he would "personally" operate on him and resolve NADLER's troublesome complaints.
198. SAMADI never informed and advised NADLER that a urology resident was going to perform the TURP unsupervised while SAMADI performed a RALP on a different patient in another O.R.
199. NADLER would never have consented to the TURP had SAMADI informed or advised him of the truthful, honest and accurate circumstances of performing the TURP.
200. Defendants SAMADI, LENOX HILL and NORTHWELL fraudulently billed Medicare, United Healthcare and NADLER for the TURP, hospitalization, anesthesia services and other related medical treatment.

201. NADLER underwent the TURP at LHH on June 22, 2015.
202. The TURP was performed by an unsupervised second year resident, Johnson Tsui, M.D., in O.R. 21 while SAMADI was performing a RALP on another patient in O.R. 25.
203. On June 22, 2015, SAMADI had “double-booked” urologic surgeries on NADLER and another patient in O.R. 21 and O.R. 25.
204. The surgery in O.R. 25 was a RALP.
205. The surgery in O.R. 21 on NADLER was a cystoscopy / TURP.
206. The two “double-booked” urologic surgeries on SAMADI’s patients in O.R. 25 and O.R. 21 on June 22, 2015, were “concurrent” surgeries and also endoscopic / laparoscopic urologic surgeries.
207. Dr. Tsui performed the TURP on NADLER in O.R. 21 on June 22, 2015, without supervision since an attending urologist was not present as required for the “entire viewing” during this endoscopic surgery and SAMADI was in O.R. 25 performing the RALP.
208. The TURP performed on NADLER in O.R. 21 was done under general anesthesia.
209. The time duration of the TURP on NADLER was excessive: 2 hours; TURPs should normally be done within a 1 hour duration.
210. SAMADI did not supervise Tsui during the TURP on NADLER since he was not present in O.R. 21 for the “entire viewing” and was not present for the “critical and key portions” of this endoscopic surgery.

211. Indeed, the operative report on NADLER's TURP on June 22, 2015, was dictated by Tsui but edited and electronically signed by SAMADI on June 29, 2015 (i.e., one week later). (See, Exhibit G, Operative Report, Peter Nadler, June 22, 2015.)
212. The NADLER operative report falsely states that SAMADI was the "surgeon" and Tsui was the "assistant surgeon".
213. The operative report for NADLER's TURP on June 22, 2015, does not state that SAMADI was present for the "critical or key portions" of the procedure or the "entire viewing" portion of the procedure.
214. Tsui also prepared an operative summary progress note for NADLER's TURP on June 22, 2015. (See, Exhibit H, Operative Summary Progress Note, Peter Nadler, June 22, 2015.)
215. According to the operative report and operative summary, there was no indication that Tsui observed any obstruction within NADLER's prostatic urethra during the cystoscopic portion of the TURP.
216. Tsui removed only 5 grams of prostatic tissue during the TURP performed on NADLER according to the surgical pathology report. (See, Exhibit I, Surgical Pathology Report, Peter Nadler, June 22, 2015.)
217. Tsui improperly performed the TURP because the 5 gram amount of tissue removed from NADLER's prostate was clearly inadequate for this surgery to be properly performed on patients with obstructive BPH; therefore, the surgical procedure that was performed by the unsupervised resident was non-therapeutic and without any medical benefit to the patient.

218. Moreover, there was no medical justification for using general anesthesia on NADLER for the TURP.

219. NADLER was not only unnecessarily subjected to general anesthesia and excessive anesthesia time; but the defendants billed for this unnecessary anesthesia service.

220. Tsui deviated from proper urology practice by failing to remove a therapeutic amount of prostatic tissue from NADLER that did not alleviate the urinary tract obstruction, but rather ultimately worsened it by causing scarring and overgrowth of BPH into the urethra.

221. NADLER did not obtain relief of his LUTS as a result of the faulty TURP by Tsui and instead postoperatively suffered more severe complaints and worsened urinary tract function than that which initially brought him to seek treatment from SAMADI.

222. The consent form for NADLER's TURP states that he consents to SAMADI performing the surgery; neither Tsui nor any other "assistant" or "resident" is specifically named or identified as the surgeon performing the surgery or even participating in it. (See, Exhibit J, Consent Form, Peter Nadler, June 22, 2015.)

Simultaneous Surgery Harmed Patient Stephen Markelson

223. Plaintiff-Relator's decedent, STEPHEN MARKELSON, was SAMADI's patient in October 2013.

224. At the time, MARKELSON, then 79 years old, was a patient covered by Medicare and private commercial health insurance through Blue Cross.

225. MARKELSON was responsible for corresponding co-payments incurred by medical expenses.

226. MARKELSON came under SAMADI's treatment for intermittent hematuria (i.e., blood in the urine) and a retained blood clot in the bladder.

227. SAMADI recommended a TURP when medical treatment failed to resolve the bleeding and scheduled MARKELSON for surgery at LHH on October 30, 2013.

228. SAMADI fraudulently led MARKELSON, his wife and son (plaintiff-relator GEORGE MARKELSON) to believe that he would personally perform the TURP.

229. SAMADI never informed and advised MARKELSON and his family that a urology resident was going to perform the TURP unsupervised while SAMADI performed RALPs on other patients in O.R. 25.

230. MARKELSON would never have consented to the TURP had SAMADI informed or advised him of the truthful, honest and accurate circumstances of a resident actually performing the TURP.

231. Defendants SAMADI, LENOX HILL and NORTHWELL fraudulently billed Medicare, Blue Cross and MARKELSON for the TURP, hospitalization, anesthesia services, and other related medical treatment.

232. MARKELSON underwent a cystoscopy / TURP at LHH on October 30, 2013.

233. The cystoscopy / TURP was performed by an unsupervised second year resident, Dr. Billy Cordon, in O.R. 21 while SAMADI was performing a RALP on another patient in O.R. 25.
234. The cystoscopy / TURP performed on MARKELSON by Cordon in O.R. 21 was entirely or completely “simultaneous” or “concurrent” with a RALP performed by SAMADI in O.R. 25 (i.e., the TURP by Cordon was encompassed by the RALP) since MARKELSON’s TURP in O.R. 21 started at 13:40 and ended at 15:50 while the other patient’s RALP in O.R. 25 started at 13:40 and ended at 17:40.
235. On October 30, 2013, SAMADI had “double-booked” seven (7) urologic surgeries on his patients in both O.R. 25 and O.R. 21.
236. The surgeries in O.R. 25 were all RALPs.
237. The surgeries in O.R. 21 were TURPs, cystoscopies and ureteroscopies.
238. The multiple “double-booked” urologic surgeries on SAMADI’s patients in O.R. 25 and O.R. 21 on October 30, 2013, were all “concurrent” or “simultaneous” surgeries except for 1 RALP.
239. The multiple “double-booked” urologic surgeries on SAMADI’s patients in O.R. 25 and O.R. 21 on October 30, 2013, were also endoscopic / laparoscopic urologic surgeries.
240. Two (2) of the multiple “double-booked” urologic surgeries and operative procedures on SAMADI’s patients in O.R. 25 and O.R. 21 on October 30, 2013, were on Medicare patients.

241. The remainder of the surgical procedures on SAMADI's were on patients whose treatment was covered under private commercial health insurance plans.
242. Dr. Cordon performed the cystoscopy / TURP on MARKELSON in O.R. 21 without supervision since an attending urologist was not present as required for the "entire viewing" during this endoscopic surgery.
243. The TURP performed on MARKELSON in O.R. 21 was done under general anesthesia.
244. The time duration of the TURP on MARKELSON was more than 2 hours.
245. SAMADI did not supervise Cordon during the TURP on MARKELSON since he could not possibly have been present in O.R. 21 for the "entire viewing" and was not present for the "critical and key portions" of this endoscopic surgery.
246. The operative report on MARKELSON's TURP falsely states that SAMADI was the "surgeon" and Cordon was the "assistant surgeon"; SAMADI signed the operative report. (See, Exhibit K, Operative Report, Stephen Markelson, October 30, 2013.)
247. SAMADI's signing of the operative report purports to certify that he performed the surgery on MARKELSON; however, he could not possibly have been present to perform the surgery because SAMADI was elsewhere in another O.R. performing a RALP on another patient at the same exact time.
248. The operative report does not state that SAMADI was present for the "critical or key portions" of the procedure or the "entire viewing" portion of the procedure.

249. The operative report indicates that MARKELSON's prostate was markedly enlarged at 150g – 200g and that he was suffering from intermittent hematuria and a retained blood clot.
250. The MARKELSON operative report indicates difficulty in controlling bleeding during the procedure.
251. Several days after MARKELSON's TURP on October 30, 2013, he returned to LHH's E.R. with severe hematuria that would not stop.
252. Subsequently, MARKELSON was brought to the operating room for an open radical prostatectomy by Jay Motola, M.D., to remove the entire prostate to stop the bleeding; Dr. Motola performed this surgery because SAMADI had left to go on a trip out of New York at the time and no other attending urologist was available to undertake this surgery.
253. SAMADI's decision to have MARKELSON undergo a TURP by Cordon was erroneous, negligent and contraindicated because the TURP was guaranteed to result in a recurrence of bleeding in this elderly patient.
254. A TURP on a prostate as large as 150g – 200g with chronic intermittent hematuria is contraindicated due to the high risk of postoperative hemorrhage.
255. Moreover, MARKELSON had a mechanical aortic valve that required daily anticoagulation medication.
256. Severe hematuria (i.e., postoperative hemorrhage) that was potentially life threatening occurred after MARKELSON's TURP because the surgery had been performed on him under contraindicated conditions.

257. Under the circumstances, an open radical prostatectomy was indicated for MARKELSON on October 30, 2013, rather than the TURP.

258. MARKELSON was also improperly subjected to general anesthesia and excessive anesthesia time on October 30, 2013; the defendants billed Medicare and private insurance for this unnecessary anesthesia service.

259. The consent form for MARKELSON's TURP states that he consents to SAMADI performing the surgery; neither Cordon nor any other "assistant" or "resident" is specifically named or identified as the surgeon actually performing the surgery or even participating in the surgery.

Evidence Indicating Samadi's Contrived "Double-Dipping" Medical Practices

260. SAMADI's actions with regard to the courses of treatment for both MARKELSON and NADLER are indicative of contrived "double-dipping" medical practices, i.e., performing certain operative procedures to ensure the subsequent necessity for a second surgery and inpatient hospital admission as a means to increase surgical volume, billing revenue and profits.

261. Contrived "double-dipping" practices are designed to ensure continued "churning" of billing revenue from patients with private health insurance or Medicare coverage.

262. SAMADI's recommendation of a TURP for an elderly patient like MARKELSON with chronic intermittent hematuria, a grossly enlarged prostate (200g) and daily anticoagulation for a mechanical aortic valve was contraindicated since it would necessarily raise a very high risk for recurrent

postoperative bleeding requiring treatment by an open radical prostatectomy and inpatient hospital admission.

263. MARKELSON did, in fact, sustain a postoperative hemorrhage, required an open radical prostatectomy, and needed to be admitted to LENOX HILL.

264. While LENOX HILL and NORTHWELL received billing revenue related to services for MARKELSON's second admission for this operation, the fortuitous circumstances of SAMADI being away from New York on a trip resulted in the billing revenue for the attending surgeon's services to go to Dr. Motola; however, the billing revenue for the inpatient hospital admission went to LENOX HILL and NORTHWELL.

265. The course of NADLER's treatment with SAMADI similarly raises the same contrived "double-dipping" issues.

266. Prior to NADLER's TURP on June 22, 2015, SAMADI had the patient undergo a prostate biopsy on May 15, 2015.

267. The prostate biopsy specimens were sent by SAMADI to Bostwick Laboratories for pathology examination and diagnosis rather than LENOX HILL's own pathology department.

268. Bostwick Laboratories has a questionable history: On January 8, 2016, the owner of Bostwick Laboratories agreed with the U.S. Department of Justice to pay a \$3.75 million settlement related to claims of Medicare and Medicaid fraud.

269. The Bostwick Laboratories' pathology report on NADLER's specimens that was sent to SAMADI not only indicated BPH (an indication for a TURP with severe obstructive lower urinary tract symptoms due to a prostatic urethral

obstruction) but also “atypical small acinar proliferation” – a cellular marker potentially indicative of early prostate cancer. (See, Exhibit L, Bostwick Laboratories, Pathology Report, May 15, 2015.)

270. During postoperative visits, SAMADI advised NADLER that he would need to undergo repeat prostate biopsies every six (6) months to check for prostate cancer due to the “atypical small acinar proliferation”.

271. NADLER eventually left SAMADI’s care in 2016 after his complaints to SAMADI about more severe postoperative LUTS symptoms went unaddressed and untreated.

272. NADLER came under the care of another LHH attending urologist, Noel A. Armenakas, M.D., who ordered a repeat prostate biopsy after reading SAMADI’s medical records and noting the Bostwick Laboratories’ pathology report finding of “atypical small acinar proliferation”.

273. Dr. Armenakas performed NADLER’s repeat biopsy on March 30, 2016, and sent the biopsy specimens to a different pathology laboratory, CBLPath, for analysis and diagnosis.

274. The CBLPath pathology report on NADLER’s biopsy specimens that was sent to Dr. Armenakas indicated that all cores showed “benign prostate tissue” and were negative for “atypical small acinar proliferation”. (See, Exhibit M, CBLPath, Pathology Report, Peter Nadler, March 30, 2016.)

275. Dr. Armenakas advised NADLER that periodic repeat prostate biopsies were not necessary since the pathology report showed that he did not have “atypical small acinar proliferation”.

276. If NADLER had remained SAMADI's patient, SAMADI and Bostwick Laboratories would have received substantial billing revenue related to NADLER's repeat prostate biopsies; however, the fortuitous circumstances of NADLER terminating the doctor – patient relationship with SAMADI and coming under the care of Dr. Armenakas led to the discovery that he did not have “atypical small acinar proliferation” and would not need to undergo repeat prostate biopsies every 6 months.

**Fraudulent General Anesthesia Services for the
Surgeries by Unsupervised Second and Third Year
Urology Residents in O.R. 21**

277. Defendants DAVID B. SAMADI, M.D., DAVID B. SAMADI, M.D., P.C., LENOX HILL HOSPITAL and NORTHWELL HEALTH, INC., fraudulently conspired to bill Medicare (and also Medicaid and private commercial health insurers) for general anesthesia services that were medically unjustifiable and excessively prolonged.

278. SAMADI ordered general anesthesia for more than 1,000 surgeries in O.R. 21 during the period 2013 – 2016 so that the patients would be unaware that their surgery was being performed by an unsupervised urology resident and SAMADI was not present in the operating room.

279. The use of general anesthesia for the vast majority of the non-RALP surgeries on SAMADI's patients in O.R. 21 is confirmed by the Northwell / LHH urologic surgery database, O.R. schedules, anesthesia records, and operative reports. (See, Exhibit B, LHH Urologic Surgery Database [Samadi], 2013 – 2016;

Exhibit C, LHH Urology Department O.R. Schedule, 2015; Exhibit D, LHH Urology Department O.R. Schedule, 2017; Exhibit E, LHH Anesthesia Records, March 4, 2015; Exhibit G, Operative Report, Peter Nadler, June 22, 2015; Exhibit K, Operative Report, Stephen Markelson, October 30, 2013.)

280. The use of general anesthesia for the surgeries performed by residents in O.R. 21 was not medically necessary or indicated under standards of proper urology practice since the surgical procedures are customarily and safely performed under spinal or epidural anesthesia with sedation.

281. The general anesthesia was also excessively prolonged for many of the surgeries in O.R. 21 since the resident performing the surgery had to await SAMADI's temporary presence in the operating room to perform the mandated "timeout" so that the surgery by the resident could commence.

282. The practice of billing for unreasonable and unnecessary general anesthesia was not a remote occurrence in the course of the foregoing fraud scheme by the defendants.

283. The general anesthesia billing practices were commonplace and a direct outgrowth of the defendants' "simultaneous surgery", "concurrent surgery" and "double booking" practices which required (1) patients to be put under general anesthesia so that they would be unaware that their surgeon, SAMADI, was not performing the operation as they had expected and under the circumstances serving as the basis of their consent to the operation; and (2) patients to be subject to surgical delays while under general anesthesia to await a mandatory "timeout" so the resident could begin the operation.

284. For this reason, virtually every claim by defendants SAMADI, SAMADI, P.C., LENOX HILL HOSPITAL and NORTHWELL for SAMADI's simultaneous / concurrent surgeries during 2013 – 2016 is not payable and is a false claim since it includes charges for unnecessary and unreasonable general anesthesia.

Fraudulent Informed Consents for the Simultaneous Surgeries by Unsupervised Second and Third Year Urology Residents in O.R. 21

285. Defendants DAVID B. SAMADI, M.D., DAVID B. SAMADI, M.D., P.C., LENOX HILL HOSPITAL and NORTHWELL HEALTH, INC., fraudulently conspired to bill Medicare (and also Medicaid and private commercial health insurers) for surgeries, anesthesia services and related medical treatment that lacked a proper informed consent.

286. The patients undergoing the urological surgeries in O.R. 21 were all defendant SAMADI's patients who were defrauded into believing that SAMADI would be performing the planned surgery on them.

287. SAMADI had specifically advised these patients that he would be personally performing their surgeries.

288. Contrary to these fraudulent representations, approximately one thousand or more of SAMADI's patients underwent surgery by unsupervised second and third year urology residents and were placed under general anesthesia without a proper informed consent.

289. During the period 2013 - 2016, defendant LENOX HILL utilized various consent forms that are signed by patients before surgery; however, none informed patients that their surgeon would not be present during the surgery because the surgeon planned or intended to perform another surgery at the same time.

290. Moreover, LENOX HILL initially used consent forms that merely required specifying the identity of the attending surgeon performing the operation; subsequently the consent form was changed to include a space requiring the insertion of the specific identities of the assistant surgeons and/or residents involved in performing the surgery.

291. For example, the operative report for NADLER's TURP identifies Johnson Tsui, M.D., as the "assistant" surgeon; however, the consent form signed by the patient does not specify that Tsui was to be the "assistant" for this surgery and it certainly does not state that Tsui was to be performing the surgery. (See, Exhibit G, Operative Report, Peter Nadler, June 22, 2015; Exhibit J, Consent Form, Peter Nadler, June 22, 2015.)

292. LENOX HILL's current consent form is the one used for the NADLER TURP in 2015; this version of the consent form fails to advise the patient that: the surgeon may be performing two surgeries at the same time, a specifically identified resident will be performing surgery with or without the supervision of the patient's attending surgeon, or the planned surgery will be part of "simultaneous", "concurrent" or "double booked" surgery practices by the attending surgeon.

293. Instead of meeting the obligation of full and proper disclosure and informed consent, defendants SAMADI, LENOX HILL and NORTHWELL actively sought to conceal their simultaneous / concurrent surgery scheme from SAMADI's patients.

294. In summary, defendant LENOX HILL's consent forms, policies and practices fail to meet criteria for informed consent required by Medicare regulations, state law, medical ethics standards, and standards of proper urology practice; therefore, surgeries billed by the defendants for all the non-RALP surgeries by unsupervised urology residents in O.R. 21 constitute non-consensual surgical treatment and false claims.

**Fraudulent Medical Records Related to the
Simultaneous Surgeries by Unsupervised
Second and Third Year Urology Residents in O.R. 21**

295. Defendants DAVID B. SAMADI, M.D., DAVID B. SAMADI, M.D., P.C., LENOX HILL HOSPITAL and NORTHWELL HEALTH, INC., fraudulently conspired to bill Medicare (and also Medicaid and private commercial health insurers) for surgeries, anesthesia services and related medical treatment that involved the preparation of fraudulent medical records (e.g., operative reports, anesthesia records, operative case records, etc.) that falsely indicated that SAMADI had either performed the surgery, was present for "the critical or key portions of the surgery", and/or was present for the "entire viewing" portion of the endoscopic / laparoscopic surgery for the operations in O.R. 21 that had been performed by the unsupervised residents.

296. For example, the operative reports for the TURPs performed on NADLER and MARKELSON falsely indicated that the “surgeon” was SAMADI, the “assistant surgeon[s]” were Johnson Tsui, M.D., and Billy Cordon, M.D., and the reports were signed by SAMADI; however, the evidence clearly demonstrates that SAMADI was involved in performing a RALP in O.R. 25 during these two endoscopic urologic surgeries in O.R. 21. (See, Exhibit B, LHH Urologic Surgery Database [Samadi], 2013 – 2016; Exhibit G, Operative Report, Peter Nadler, June 22, 2015; Exhibit K, Operative Report, Stephen Markelson, October 30, 2013.)

297. Moreover, the operative reports for the NADLER and MARKELSON surgeries did not state that SAMADI was present in the O.R. for the “critical or key portions” of the surgery or the “entire viewing” portion of these endoscopic / laparoscopic operations.

298. Finally, the operative reports for NADLER and MARKELSON fail to specify the identity of an available qualified teaching physician, i.e., “backup attending surgeon”, who was actually available to take over the surgery from the residents if necessary.

299. None of the medical records for NADLER or MARKELSON surgeries maintained by LHH would have allowed a regulator to clearly infer that SAMADI or the teaching physician was immediately available to return to either surgery in the event of complications.

300. The investigation undertaken by the plaintiff-relators’ attorneys revealed evidence indicating that none of the LENOX HILL medical records related to the “simultaneous” or “concurrent” non-RALP surgeries by the urology residents in

O.R. 21 contain the foregoing requisite information and instead falsely indicate that SAMADI was the surgeon performing the operative procedure.

301. The investigation undertaken by the plaintiff-relators' attorneys revealed evidence indicating that none of the LENOX HILL medical records related to the "simultaneous" or "concurrent" non-RALP surgeries by the urology residents in O.R. 21 accurately reflects who actually performed the surgery; instead the records are silent, misleading, untruthful or entirely false and/or contain significant omissions.

Northwell, Lenox Hill Hospital and Samadi Were Well Aware of Medicare and Medicaid Violations and Resulting Potential False Claim Liability

Northwell's Compliance & Ethics Policy

302. NORTHWELL's own compliance and ethics policy, in force since 2007, emphasizes the necessity for full compliance with all Medicare and Medicaid laws, regulations, rules and requirements and cautioned that a failure to comply with such rules had serious repercussions that included violations of the U.S. False Claims Act and New York State False Claims Act that could result in "significant civil and/or criminal penalties". (See, Exhibit N, Northwell Compliance & Ethics Policy.)

303. NORTHWELL's compliance policy specifically applies to all of its facilities, including LENOX HILL, all employees and the medical staff, including SAMADI.

304. NORTHWELL's compliance policy specifically indicates that its workforce was educated about "Northwell Health policies, [and] the

requirements, rights and remedies of Federal and state laws governing the submission of false claims.”

305. Thus, defendants were fully knowledgeable and aware that the foregoing actions violated Medicare (and Medicaid) regulations and yet NORTHWELL HEALTH and LENOX HILL HOSPITAL authorized, approved, permitted, allowed, ratified, enabled, equipped, supported, assisted, encouraged, and promoted SAMADI’s fraudulent conduct at issue.

306. NORTHWELL’s compliance policy, in pertinent part, states the following:

“GENERAL STATEMENT of PURPOSE

It is the obligation of the Northwell Health and its affiliated entities (“Northwell Health”) to prevent and detect any actions within the organization that are *illegal, violative of federal and state health care programs (Medicare, Medicaid and other governmental payer programs), fraudulent* or in violation of any applicable Northwell Health policy.

To this end, Northwell Health maintains a vigorous Compliance Program and strives to *educate our work force regarding Northwell Health policies, the requirements, rights and remedies of Federal and state laws governing the submission of false claims*, including the rights of employees to be protected as whistleblowers under such laws and the importance of submitting accurate claims and reports to federal and state governments.

POLICY

Northwell Health *prohibits the violation of state and federal law, applicable Northwell Health policy and the knowing submission of a false claim for payment in relation to a federal or state-funded health care program. Such a submission violates the federal False Claims Act as well as various state laws, and may result in significant civil and/or criminal penalties.*

SCOPE

This policy applies to all Northwell Health *employees*, as well as *medical*

staff, volunteers, students, trainees, physician office staff, contractors, trustees and other persons performing work for or at Northwell Health;”

(See, Exhibit N, Northwell Compliance & Ethics Policy [emphasis added].)

307. Under the circumstances detailed above regarding corporate compliance policy, defendants DAVID B. SAMADI, M.D., DAVID B. SAMADI, M.D., P.C., LENOX HILL HOSPITAL and NORTHWELL HEALTH, INC., knowingly, intentionally and purposefully submitted claims for payment to Medicare containing false statements, misrepresentations, misleading assertions, omissions and “half-truths” that concealed violations of Medicare statutory, regulatory, and/or contractual requirements with respect to the foregoing medical services provided to covered patients.

308. Under the circumstances detailed above regarding knowledge and familiarity with Northwell’s compliance and ethics policy, it is apparent that the defendants knew, had reason to know and even expected that the Medicare program would consistently refuse to pay such claims based on noncompliance with the applicable Medicare regulations if the claims submitted in relation to the simultaneous / concurrent surgeries by the unsupervised residents in O.R. 21 were truthful and accurate.

**Lenox Hill Hospital’s Belated Attempt to
Develop an Overlapping Surgery Policy
And Aborted Implementation**

309. In response to an article in the Boston Globe’s Spotlight section published on March 12, 2017, about SAMADI’s “simultaneous”, “concurrent” and

“overlapping” surgical practices¹⁹, the LENOX HILL medical board issued a bulletin that advised hospital employees and staff that it was developing an “Overlapping Surgery” policy that required NORTHWELL’s approval before implementation. (See, Exhibit O, LHH Medical Board Bulletin, March 19, 2017.)

310. There have been no further notices or bulletins regarding the planned LHH “Overlapping Surgery” Policy published for hospital employees and staff, no distribution of such a policy to date, and no indication that NORTHWELL executives will ever approve such a policy that could restrict or limit simultaneous / concurrent surgery practices using unsupervised residents.

The Motives of Increased Surgical Volume, Revenue, Profits and Compensation Underly the Defendants’ Fraud Scheme

311. SAMADI was hired by LENOX HILL and NORTHWELL for the purpose of enhancing the health systems expansion and competitiveness. (See, Exhibit P, “New York’s \$9.6 million man and other top health earners”, G. Schiffman, Crain’s NY Business, April 13, 2016.)

312. SAMADI was hired by LENOX HILL and NORTHWELL pursuant to an employment contract with augmentation bonus and incentive clauses based on surgical volume and revenue. (See, Exhibit P, “New York’s \$9.6 million man and other top health earners”, G. Schiffman, Crain’s NY Business, April 13, 2016.)

¹⁹ (See, J. Saltzman & J. Abelson, Star Surgeon is Scrutinized on Concurrent Procedures, Boston Globe, March 12, 2017.)

313. By 2016, SAMADI's compensation had increased by \$2.9 million under this contract. (See, Exhibit P, "New York's \$9.6 million man and other top health earners", G. Schiffman, Crain's NY Business, April 13, 2016.)
314. A NORTHWELL executive referred to SAMADI as "prolific in [his] field" and acknowledged that his compensation increase was "tied to [his] responsibility and [his] importance to the organization" with compensation that is "competitive but justifiable in terms of [his] value to the system". (See, Exhibit P, "New York's \$9.6 million man and other top health earners", G. Schiffman, Crain's NY Business, April 13, 2016.)
315. The investigation by plaintiff-relators' attorneys revealed evidence corroborating that the primary motive of the fraudulent simultaneous / concurrent surgery scheme perpetrated by SAMADI, LENOX HILL and NORTHWELL was to increase surgical volume and, thereby, increase revenue, profit and physician compensation.
316. During LENOX HILL's 2015 urology residency graduation ceremony, SAMADI presented graphs and statistics along with his own commentary boasting about the "increasing volume at Lenox Hill" for "overall all robotic cases at Lenox Hill" and "all urological cases over the past 5 years" and also voiced optimistic expectations that "[i]n the next 5 months we expect volume to persist, and surpass last year's numbers". (See, Exhibit Q, LENOX HILL Urology Residency Graduation Ceremony, "Prezi" Transcript; Exhibit R, LENOX HILL Urology Residency Graduation Ceremony, "Prezi" Video Presentation Panels.)

317. During the foregoing ceremony, SAMADI also self-servingly commented that a “total of 865 prostatectomies were performed at LHH within the last 2 years!” Id.

318. More telling, during the foregoing ceremony, SAMADI also enthusiastically exclaimed that an “increase in overall volume means more: TURPs, lithotripsies, nephrectomies, penile implants” and that “[t]his achievement is made possible in large part by our residents: Billy Cordon, M.D., Yaniv Larish, M.D., Johnson Tsui, M.D., Shawn Mendonca, M.D.” (See, Exhibit Q, LENOX HILL Urology Residency Graduation Ceremony, “Prezi” Transcript; Exhibit R, LENOX HILL Urology Residency Graduation Ceremony, “Prezi” Video Presentation Panels.)

319. The same information stated by SAMADI was displayed in a video presentation known as a “Prezi” display shown at the graduation ceremony. (See, Exhibit R, LENOX HILL Urology Residency Graduation Ceremony, “Prezi” Video Presentation Panels.)

320. SAMADI maintains a “white board” in O.R. 25, the operating room that is reserved for the RALPs that he performs on patients at LENOX HILL; this “white board” keeps a running tally of the total number of RALPs performed since “7-13-13” at the beginning of the day, the total number of RALPs performed that particular operating day (e.g., “1-23-17”), and the new total number of RALPs since “7-13-13” at the end of the day. (See, Exhibit S, Samadi’s O.R. 25 “White Board” RALP Tallies.)

Northwell / Lenox Hill Hospital's Department of Urology

321. Defendant LENOX HILL HOSPITAL describes itself as “a 652-bed, acute care hospital located on Manhattan's Upper East Side” that is a “staple in the community for more than 150 years”, and further describes that its “mission is to deliver outstanding healthcare with compassion and respect, to promote wellness in its communities, and to advance the field of medicine through education and research”.

322. Defendant LENOX HILL HOSPITAL's department of urology is staffed by numerous board certified attending urologists some of whom are employees of LENOX HILL and NORTHWELL and some of whom are non-employee attending urologists with their own private practices and privileges to admit patients to the hospital for urologic treatment including surgery and other operative procedures.

323. Defendants LENOX HILL and NORTHWELL heavily advertise defendant SAMADI's urology services; purportedly spending approximately \$70,000.00 a month primarily for internet advertising related to SAMADI's services.

324. For example, the “department of urology” on defendant LENOX HILL's website directs to a page that touts only defendant SAMADI's services, the contact information for SAMADI's private urology practice (i.e., DAVID B. SAMADI, M.D., P.C.), and provides various resource links directed to “Lenox Hill Prostate Cancer Center” and “Robotic Oncology.com”.

325. “Lenox Hill Prostate Cancer Center” and “Robotic Oncology.com” also exclusively advertise defendant SAMADI’s services and similarly provide the contact information for SAMADI’s private urology practice.

326. “Lenox Hill Prostate Cancer Center” and “Robotic Oncology.com” are merely “trade names” and “d/b/a’s” for DAVID B. SAMADI, M.D., P.C.

327. The only other attending urologists identifiable and advertised on defendant LENOX HILL HOSPITAL’s website are Boback M. Berookhim, M.D., and Michael Feuerstein, M.D.

328. Boback M. Berookhim, M.D., and Michael Feuerstein, M.D., are defendant SAMADI’s business associates and employees of defendant SAMADI, P.C.

Northwell / Lenox Hill Hospital’s Urology Residency Program

329. Defendant LENOX HILL HOSPITAL is affiliated as a teaching hospital with the Hofstra Northwell School of Medicine and offers “residency and fellowship training programs in most of its clinical areas”.

330. Defendant LENOX HILL offers a urology residency program that “consists of an ACGME accredited four-year program with one resident in each year” with a prerequisite two years of post-graduate training in general surgery at hospital.

331. Defendant LENOX HILL’s urology residency program is the responsibility of defendant SAMADI who assumed the directorship after he was hired by NORTHWELL to be the urology department chairman in 2013.

332. The American College of Graduate Medical Education (i.e., ACGME) provides accreditation of all residency and fellowship training programs at teaching hospitals in the United States; the ACGME periodically evaluates, assesses and inspects all such residency and fellowship programs.

333. Under SAMADI's leadership, defendant LENOX HILL's urology residency program was given a warning but then was placed on probation by the ACGME, with the possibility of revocation of its accreditation due to residency training deficiencies discovered by an ACGME audit. (See, Exhibit F, ACGME Accreditation Status for Urology Residency Program at Northwell Lenox Hill Hospital).

334. The residency program deficiencies that led to the current ACGME probationary status are a consequence of the defendants' fraudulent simultaneous / concurrent surgery scheme to inflate surgical volume, billing revenue, health system profit and physician compensation through, in significant part, the exploitation of urology residents to perform unsupervised non-RALP surgeries while SAMADI maximizes total RALP surgeries.

335. The defendants' fraudulent simultaneous / concurrent surgery scheme was undertaken at the expense of proper and comprehensive urology residency training.

336. Defendant LENOX HILL states that its residency and fellowship programs operate under the comprehensive philosophy that the "best way in which new physicians can be trained is through hands-on experience"; however, it does not describe exactly how residents receive this "hands on experience".

337. As urology residency program director, SAMADI apparently interpreted the “hands on experience” methods to mean unsupervised residents performing surgeries on his unsuspecting patients.

**Federal Support of Northwell / Lenox Hill’s
Urology Residency Program**

338. Defendants LENOX HILL HOSPITAL and NORTHWELL serve as the “institutional sponsor” for the urology residency program accredited by the Accreditation Council of Graduate Medical Education (i.e., ACGME) and provide salary and benefits to the urology residents.

339. The urology residents are physicians with M.D. degrees who come to LENOX HILL to train for two years in general surgery and four years in urology.

340. One urology resident per year is chosen to train through LENOX HILL’s residency program so that there are a total of four urology residents training at any one time in the program.

341. As providers of graduate medical education (“GME”), defendants LENOX HILL and NORTHWELL receive substantial payments from the United States government for resident physician training²⁰ and salaries through direct and indirect graduate medical education payments under Medicare Part A.

²⁰ A resident is a medical school graduate engaged in in-depth training in a medical specialty, which may last from 3-5 years depending upon the specialty. Residents are to be supervised by teaching physicians, also called “attending physicians”, who approve their decision-making. According to the ACGME, a “resident” is “[a]ny physician in an accredited graduate medical education program, including interns, residents, and fellows.” The ACGME defines a “fellow” as a physician in a program of graduate medical education accredited by the ACGME who has completed the requirements for eligibility for first board certification in the specialty. The term “subspecialty residents” is also applied to such physicians. Other uses of the term “fellow” require modifiers for precision and clarity, e.g., “research fellow”. See, ACGME Glossary of Terms (Glossary of Terms, July 1, 2013); http://acgmewcb/Portals/O/PFAssets/ProgramRequirements/ab_ACGMEglossary.pdf.

342. In addition, defendants LENOX HILL and NORTHWELL receive funding from other federal payers and state Medicaid programs (collectively with payments under Medicare A “GME funds”) to support their work in training residents²¹.

343. The GME funds provided by federal sources for graduate medical education are significant; for example, Medicare contributed \$9.5 billion to teaching hospitals in the United States in 2010 to support the training of about 100,000 residents²².

344. Defendants LENOX HILL and NORTHWELL bill Medicare Part B for the services (such as surgeries) rendered by teaching physicians on its faculty incident to the instruction of residents provided that all Medicare (and Medicaid) regulations are followed.

CPT Codes

345. The false claims for payment submitted by defendants in relation to the simultaneous / concurrent surgery scheme included the CPT codes that define the specific operative procedures involved in the defendants’ fraudulent simultaneous / concurrent surgery scheme for the purposes of determining the applicable payment or reimbursement rate.

346. The CPT codes for the urologic surgeries involved in the defendants’ false claims submitted to Medicare are set forth in the annexed “Available CPT Codes

²¹ Medicare Financing of Graduate Medical Education, Intractable Problems, Elusive Solutions, Rich, E.C., et al., J. Gen. Int. Med., 17: 283-292 (2002).

²² The Uncertain Future of Medicare and Graduate Medical Education, Ingelhart, J.K., NEJM, 365:14:1340 (2011).

by Area and Type for Urology” issued by the ACGME. (See, Exhibit T, ACGME Available CPT Codes by Area and Type for Urology.)

347. The plaintiff-relators incorporate by reference the specific CPT codes for each of the surgical procedures performed on the defendants’ patients by unsupervised urology residents in O.R. 21, as indicated in the annexed LENOX HILL urologic surgery database, O.R.schedules and anesthesia records, that constitute false claims under the U.S. False Claims Act. (See, Exhibit B, LHH Urologic Surgery Database [Samadi], 2013 – 2016; Exhibit C, LHH Urology Department O.R. Schedule, 2015; Exhibit D, LHH Urology Department O.R. Schedule, 2017; Exhibit E, LHH Anesthesia Records, March 4, 2015; Exhibit T, ACGME Available CPT Codes by Area and Type for Urology.)

**Samadi’s Recent “Flexible Fee” Approach to Prostate Surgery:
Price: \$58,000 - \$10,000, Payment Method: Cash or Credit Card**

348. In January 2016, a patient in his 70’s, a retired insurance company executive, consulted SAMADI for the treatment of prostate cancer after reading some of the defendant’s internet advertisements.

349. The patient was a Medicare beneficiary and also covered by a private commercial insurance policy.

350. In February 2016, SAMADI recommended that the patient undergo a RALP and the man agreed to that treatment plan.

351. SAMADI advised him to consult the personnel in his office at SAMADI, P.C., to make scheduling and “financial” arrangements.

352. The patient was told by office personnel that the surgery could not be scheduled until April 2016.

353. Initially, SAMADI's office personnel advised the patient that "Dr. Samadi's fee is \$58,000 for the operation" and he was further advised that the fee was payable in cash or credit card and had to be paid one week prior to surgery.

354. When the patient balked at the price quote for the \$58,000 fee, SAMADI's office personnel eventually sent him an email in late February advising that SAMADI's surgical fee had been lowered to \$10,000.

355. SAMADI, P.C.'s email states: "As of April 1st Dr. Samadi will no longer be par with Medicare there for *[sic]* your surgery will be considered self-pay. Due to the last minute disenrollment with Medicare Dr. Samadi is *discounting his \$58,000 surgical fee to \$10,000* for his established patients." (See, Exhibit W, SAMADI, P.C., E-Mail Message [emphasis added].)

356. The patient was subsequently advised that the discounted \$10,000 surgical fee was still payable in its entirety by cash or credit card prior to the surgery; the patient opted to pay the \$10,000 amount by credit card to "North Shore / LIJ Urology – Samadi" as instructed by SAMADI's office staff.

357. The Medicare schedule fee for RALPs is \$1,700 and the program pays 80% of the cost.

358. SAMADI performed a RALP on the man in April 2016; the man has suffered urinary incontinence since this operation.

359. Another patient, a 58 year old man from New Jersey, consulted SAMADI for prostate cancer in 2015, a RALP was recommended by SAMADI, and the

patient was told that SAMADI accepted his Blue Cross insurance; Blue Cross paid a \$2,500 fee for a RALP at the time.

360. Subsequently, SAMADI's office mailed to the patient a "pre-surgical information packet" advising that he was to fill out an information sheet and include a check in the amount of \$10,000 for the surgical fee; a follow up phone call by a staffer from SAMADI's office several days later asked the patient when the doctor could expect him to send the \$10,000 check for the surgical fee.

361. When the patient balked at the \$10,000 surgical fee in excess of the insurance reimbursement, SAMADI's office staff subsequently called back to advise him that SAMADI would accept just the insurance fee amount.

362. Insulted and unnerved by SAMADI's brazen attempt to extract an excess surgical fee contrary to the health plan provisions, the patient from New Jersey opted to undergo a RALP at UPenn Presbyterian Hospital in Philadelphia, PA, by David Lee, M.D., who charged only the Blue Cross \$2,500 fee for the surgery and follow up postoperative visits.

Original Source

340. Plaintiff-relators' are the "original source" of the claims in this action and the information and evidence set forth in this Complaint, including its annexed Exhibits A – W, pertaining to the defendants' pattern of fraudulent conduct and consequent violations of Medicare regulations pursuant to 31 U.S.C. § 3730(e)(4)(B).

341. Plaintiff-relators recently came to suspect that defendant SAMADI had not performed the TURPs on STEPHEN MARKELSON in October 2013 and PETER NADLER on June 22, 2015, for several reasons and brought these suspicions to the attention of counsel.

342. Beginning in April 2016, plaintiff-relators' attorneys commenced an investigation on the behalf of clients into the allegations that defendants SAMADI, SAMADI, P.C., LENOX HILL HOSPITAL and NORTHWELL were defrauding patients by operating a "simultaneous" / "concurrent" surgery scheme involving O.R. 25 and O.R. 21, using unsupervised second and third year urology residents to perform non-RALP endoscopic / laparoscopic surgeries, and improperly billing Medicare, Medicaid, private insurance companies and the patients themselves.

343. As a result of the investigation by plaintiffs-relators' attorneys, evidentiary material was obtained from various sources, including annexed Exhibits A – W and the factual information set forth in this Complaint, substantiating the allegations in this matter.

344. Plaintiff-relators' claims as set forth in this Complaint are not based upon prior public disclosures of allegations or transactions in (1) a federal criminal, civil, or administrative hearing in which the federal government is already or has been a party, in a Congressional committee hearing or Government Accountability Office audit; (2) federal government report, hearing, audit, or investigation; and/or (3) a news media report, article, segment and/or publication under 31 U.S.C. § 3730(c)(4)(A).

345. To the extent that there has been a public disclosure unknown to plaintiff-relators of any of the exhibits annexed to this Complaint, the plaintiff-relators are the “original source” under 31 U.S.C. § 3730(e)(4)(B) for such a disclosure.

346. Plaintiff-relators have independent material knowledge of the information and evidence that serves as the basis for the allegations in this Complaint as a result of their attorneys’ investigation.

347. Plaintiff-relators voluntarily provided the information and evidence set forth in this Complaint and its annexed Exhibits A – W to the federal government before filing this *qui tam* action (see, discussion, *infra*).

348. If all or part of the factual evidence or allegations set forth in this Complaint and its annexed exhibits have been publicly reported in the media or are now the subject of investigations by governmental or official agencies, departments and/or officers, the factual basis of such media reports or governmental investigations directly or indirectly results from the information obtained as a result of the investigation of this matter by plaintiff-relators’ attorneys that commenced in April 2016.

349. The undersigned counsel’s investigation revealed Exhibits A – W and the factual information from evidentiary sources set forth in the Complaint corroborating the defendants’ fraud scheme by November 2016, except for the two exhibits generated in 2017 that were obtained by plaintiff-relators’ attorneys. (See, Exhibit D, LHH Urology Department O.R. Schedule, 2017; Exhibit O, LHH Medical Board Bulletin, March 19, 2017.)

Materiality

350. The claims in this case under the U.S. False Claims Act are material as this term is defined by statute and the federal courts. See, *Universal Health Services, Inc., v. United States and Massachusetts, ex rel. Escobar and Correa*, 579 U.S. ___, 136 S.Ct. 1989, 195 L.Ed.2d 348, 84 USLW 4410 (2016).

351. The defendants Medicare violations are material for the following reasons:

352. The defendants submitted claims to Medicare that impliedly certified compliance with all conditions of payment and requested payment or reimbursement of these claims under the program; however, (1) the claims made specific false statements, misrepresentations, misleading assertions, omissions or “half-truths” about the medical services provided; and (2) the defendants’ claims failed to truthfully disclose noncompliance with Medicare statutory, regulatory, and/or contractual requirements but rather were tainted by contained false statements, misrepresentations, misleading assertions, omissions or “half-truths”. (31 U.S.C.A. § 3729(a)(1)(A).)

353. The defendants’ false statements, misrepresentations, misleading assertions, omissions or “half-truths” about the claims for medical services provided were “false or fraudulent claims” pursuant to the U.S. False Claims Act (FCA) and constituted actionable misrepresentations under the statute. (31 U.S.C.A. § 3729(a)(1)(A).)

354. The defendants’ false statements, misrepresentations, misleading assertions, omissions or “half-truths” about compliance with Medicare statutory, regulatory, or contractual requirements were material to the government's

payment decision; therefore, these false claims were actionable under the False Claims Act (FCA). (31 U.S.C.A. § 3729(a)(1)(A), § 3729 (b)(4).)

355. The defendants' false statements, misrepresentations, misleading assertions, omissions or "half-truths" about compliance with Medicare statutory, regulatory, or contractual requirements were "material" since (1) they would have been sufficiently important to lead to denials of payments on the claims, and (2) the defendants knew or had reason to know that the Medicare program would have consistently refused to pay such claims based on noncompliance with the particular Medicare statutory, regulatory, or contractual requirement. (31 U.S.C.A. § 3729(a)(1)(A), § 3729(b)(4).)

356. Defendants' own compliance policy emphasized full compliance with all Medicare and Medicaid laws, regulations, rules and requirements and cautioned that a failure to comply with such rules had serious repercussions, including civil and criminal penalties and liability under the U.S. False Claims Act. (31 U.S.C.A. § 3729(a)(1)(A), § 3729(b)(4).)

357. Thus, defendants were fully knowledgeable and aware that the foregoing actions violated Medicare regulations and could invoke False Claims Act liability; however, NORTHWELL HEALTH and LENOX HILL HOSPITAL authorized, approved, permitted, allowed, ratified, enabled, equipped, supported, assisted, encouraged, and promoted SAMADI's fraudulent conduct. (31 U.S.C.A. § 3729(a)(1)(A), § 3729(b)(4).)

358. There is no evidence to suggest that the federal government pays in full claims such as those submitted by defendants despite actual knowledge that the

foregoing Medicare requirements were violated. (31 U.S.C.A. § 3729(a)(1)(A), § 3729(b)(4).)

359. The centrality of the violated regulations to the core of the Medicare regulatory scheme is underscored not only by their inclusion as a condition of participation but also by the fact that compliance is a prerequisite for Medicare reimbursement.

360. The centrality of the violated regulations is also underscored by the extensive interpretive guidelines issued by CMS.

361. CMS was not content to leave limitations on concurrent surgeries open to the interpretation of hospitals, doctors or other health care providers including the defendants. See, 42 CFR 415.170 & 42 CFR 415.172(a).

Prior Notice

362. Plaintiff-relators disclosed and gave notice of the allegations of this *qui tam* Complaint to the United States government prior to filing the Complaint under seal by serving a “disclosure statement” in the form of a detailed letter describing the fraudulent conduct at issue, a copy of this Complaint, and all evidentiary material referenced in the foregoing statement and pleadings via express delivery on the Attorney General of the United States, U.S. Department of Justice, 950 Pennsylvania Avenue NW, Washington, DC 20530-0001, and U.S. Attorney, Southern District of New York, 1 St. Andrew’s Plaza, New York, NY 10007. (See, Exhibit U, Letter to USDOJ & USAO/SDNY, September 29, 2017.)

The Medicare Program: Background

360. The federal government, through Medicare, is among the principal payers responsible for reimbursing defendants LENOX HILL and NORTHWELL for surgical related services.
361. Medicare is a federal government health program that primarily benefits the elderly and disabled.
362. Congress created Medicare in 1965 when it adopted Title XVIII of the Social Security Act.
363. Medicare is administered by CMS, which is an agency of the Department of Health and Human Services (“HHS”).

Medicare Parts A & B

375. To participate in the Medicare program, hospitals enter “provider agreements” with the HHS Secretary. (See, 42 U.S.C. 1395cc.)
376. Medicare Part A covers the cost of inpatient hospital services and post-hospital skilled nursing facility care, and medical insurance.
377. Medicare Part B covers the costs of the physician’s services such as services to patients who are hospitalized, if the services are medically necessary and personally provided by the physician.
378. CMS establishes rules for the day-to-day administration of Medicare.
379. CMS contracts with private companies to handle day-to-day administration of Medicare.

380. CMS, through contractors, maintains and distributes fee schedules for the payment of physician services; these schedules specify the amounts payable for defined types of medical services and procedures.

381. Hospitals are generally reimbursed under Medicare Part A on a reasonable cost basis for services provided to Medicare beneficiaries.

382. Residents' salaries are included among the costs for which hospitals are reimbursed under Medicare Part A; therefore, services provided by residents cannot be billed under Medicare Part B.

Applicable Medicare Regulations

383. As a teaching hospital engaged in the training of medical students, residents and fellows ("trainees"), defendants LENOX HILL and NORTHWELL are eligible to be reimbursed for the teaching activities of clinical faculty physicians ("teaching physicians").

384. Teaching hospitals may also properly bill under Medicare Part B for medical services of attending physicians in limited circumstances where the attending physician is directly involved in providing patient services.

385. The Medicare program pays the hospital directly for covered inpatient and outpatient services provided to Medicare beneficiaries, except for any deductible or coinsurance, which are collected from the beneficiaries.

386. When submitting claims for reimbursement to Medicare, the provider is required on CMS Form 1500 to certify, inter alia, that: 1) the information on this form is true, accurate and complete; 2) sufficient information is provided to allow

the government to make an informed eligibility and payment decision; 3) the claim complies with all applicable Medicare and/or Medicaid laws, regulations and program instructions for payment; and 4) the services on the form were medically necessary.²³

387. The form further requires the provider to certify that the services on the form were “personally furnished by me or were furnished incident to my professional service by my employee under my direct supervision, except as otherwise expressly permitted by Medicare”.

**Medicare Regulations Pertaining to Reimbursement for
Surgical Services of Attending Physicians &
Surgeons in a Teaching Setting**

388. In a teaching setting like LENOX HILL HOSPITAL, in order to receive payment under Medicare Part B for services performed by a physician, the service must meet one of the following criteria: (a) the services are personally furnished by a physician who is not a resident; or (b) the services are furnished by a resident in the presence of a fully licensed teaching physician. (Sec, 42 C.F.R. 415.170.)

389. The Medicare regulations define the circumstances that satisfy the requirement of “the presence of a fully licensed teaching physician” that permit billing by the teaching physician for surgical or operative services furnished by a resident.

390. If a resident participates in a service furnished in a teaching setting, the service is eligible for a physician fee schedule payment “only if a teaching

²³ CMS Form 1500 is available at <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf> (last visited April 25, 2017).

physician is present during the key portion of any service or procedure for which payment is sought”. (See, 42 C.F.R. 415.172(a).)

391. CMS²⁴ regulations require that the “teaching physician”, i.e., attending surgeon, “must be present during all critical and key portions of the procedure and be immediately available to furnish services during the entire procedure.”²⁵

392. The attending surgeon’s “presence is not required during the opening or closing of the surgical field unless these activities are considered to be critical or key portions of the procedure”.²⁶

393. Thus, residents or fellows may open or close the surgical field and complete the non-critical portions of the surgery without the attending surgeon present in the O.R. if they are considered non-critical portions of the procedure.²⁷

394. Once the attending surgeon has left the O.R., CMS regulations require him/her to either be immediately available to assist the resident should the need arise or arrange for another qualified surgeon to be immediately available to assist the resident.²⁸

395. CMS will not pay for surgeries where the critical or key portions of each surgery take place simultaneously, i.e., at the same time; this is generally referred to as “concurrent surgeries”, “overlapping surgeries”, “simultaneous surgeries”, “double booked surgeries” and other similar terms.

²⁴ “CMS” as used in this Complaint refers to the Centers for Medicare & Medicaid Services.

²⁵ See, CMS Manual System, Pub 100-04, U.S. Department of Health & Human Services (DHHS), Centers for Medicare & Medicaid Services (CMS), Medicare Claims Processing, Transmittal 2303, dated Sept. 14, 2011, “Teaching Physician Services”, Ch. 12, Sec. 100, Subsec. 100.1.2, Surgical Procedures (hereinafter cited as “CMS 2011 Medicare Claims Processing Manual”)

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

396. Moreover, CMS will not pay for endoscopic / laparoscopic surgeries (e.g., RALPs, TURPs, cystoscopy, ureteroscopies, etc.) in which the teaching physician / attending surgeon was not present for the “entire viewing” in the O.R.; “the entire viewing starts at the time of insertion of the endoscope and ends at the time of removal of the endoscope.”²⁹

397. In all surgical or operative procedures – such as the operations described in this Complaint – the teaching physician must be present during all critical portions of the procedure and immediately available to furnish services during the entire surgery or operative procedure. (See, 42 C.F.R. 172(a)(1).)

398. If a teaching physician engages in two surgeries that overlap, the CMS Medicare Claims Processing Manual states: “[t]he critical or key portions may not take place at the same time. When all of the key portions of the initial procedure have been completed, the teaching surgeon may begin to become involved in a second procedure”. (See, CMS 2011 Medicare Claims Processing Manual, 100.1.2-A, Surgical Procedures.)

399. Moreover, “during non-critical or non-key portions of the surgery, if the teaching surgeon is not physically present, he/she must be immediately available to return to the procedure, i.e., he/she cannot be performing another procedure”. (See, CMS 2011 Medicare Claims Processing Manual, 100.1.2-A, Surgical Procedures)³⁰.

400. When a teaching physician is participating in a second surgical procedure and “not present during non-critical or non-key portions of the [prior] procedure

²⁹ *Id.*

³⁰ Available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf> (last viewed on May 16, 2017).

.... he/she must arrange for another qualified surgeon³¹ to immediately assist the resident in the other case should the need arise”. (See, CMS 2011 Medicare Claims Processing Manual, 100.1.2-A, Surgical Procedures.)

401. Likewise the federal regulations specify that a teaching physician will not be paid if he is not present or immediately available to return to the surgery. (See, 42 CFR 415.172(a)(1).)

402. Specifically, “[d]uring non-critical or non-key portions of the surgery, if the teaching surgeon is not physically present, he/she must be immediately available to return to the procedure, i.e., he/she cannot be performing another procedure.” (See, CMS 2011 Medicare Claims Processing Manual, 100.1.2-A, Surgical Procedures.)

403. Thus, once the surgeon has left the first surgery and is engaged in another surgery, he cannot return to the first surgery and receive payment.

404. More important, Medicare regulations applicable to teaching physicians participating in endoscopic or laparoscopic surgical procedures on patients in a teaching setting that includes the participation of residents base eligibility for a physician fee schedule payment on the following: “the teaching physician must be present for the entire viewing” in the O.R.; “the entire viewing starts at the time of insertion of the endoscope and ends at the time of removal of the endoscope.”³²

405. The regulations specifically state that “[v]iewing of the entire procedure through a monitor in another room does not meet the teaching physician presence

³¹ CMS regulations require participating hospitals to “assure that personnel are licensed or met other applicable standards that are required by state or local laws”. 42 C.F.R. 482.11(c) (Condition of participation. Compliance with Federal, State and local laws).

³² See, CMS 2011 Medicare Claims Processing Manual, 100.1.2-A.5, Surgical Procedures.

requirement”; therefore, the “teaching physician” must be physically present in the O.R. supervising the resident for the “entire viewing” portion of an endoscopic or laparoscopic surgical procedure. (See, CMS 2011 Medicare Claims Processing Manual, 100.1.2-A.5, Surgical Procedures.)

406. As summarized in the U.S. Senate, Finance Committee’s report, “Concurrent and Overlapping Surgeries: Additional Measures Warranted”,³³

CMS defines “concurrent surgeries” (i.e., “simultaneous surgeries”) as those where the critical or key portions of the two or more surgeries are performed by the teaching physician at the same time. The teaching physician is not allowed to bill for such “concurrent surgeries” or “simultaneous surgeries”.

(See, Exhibit V, U.S. Senate, Finance Committee, “Concurrent and Overlapping Surgeries: Additional Measures Warranted”, December 6, 2016, [Appendix].)

407. The Senate report notes that overlapping surgeries are permitted as follows:

“[The] teaching physician must be present during the critical or key portions of both procedures. The teaching physician may become involved in a second procedure when the key portions of the initial procedure have been completed. If the teaching physician is not present during non-critical and non-key portions and is participating in another surgical procedure, she/he must arrange for another qualified surgeon to immediately assist in the other case should the need arise”.

(Id.)

408. More germane to the majority of the surgeries at issue in this case, Medicare regulations require that, in order to be eligible for a physician fee schedule payment, “the teaching physician must be present for the entire viewing” in the O.R.; and that “the entire viewing starts at the time of insertion of the

³³ Available at www.finance.senate.gov/imo/media/doc/Concurrent%20Report%20Final.pdf.

endoscope and ends at the time of removal of the endoscope.”³⁴ (See, CMS 2011 Medicare Claims Processing Manual, 100.1.2-A.5, Surgical Procedures.)

409. CMS will not pay the fee for the teaching physicians services during surgeries performed, in whole or in part, by residents if the conditions are not met pertaining to their presence in the O.R. during “the critical or key portions” of the surgery and the “entire viewing” during endoscopic / laparoscopic surgery. (See, Exhibit V, U.S. Senate, Finance Committee, “Concurrent and Overlapping Surgeries: Additional Measures Warranted”, December 6, 2016 [Appendix].)

410. The Senate report notes that the American College of Surgeons (ACS) confirmed the CMS guidelines in its own clinical guidelines issued in April 2016 and remarks that the ACS guidelines reflect what is necessary for patient safety.

411. CMS policy expressly limits payment to services for which there is documentation demonstrating the appropriate service level required by the patient. (See, Medicare Carriers Manual, Part 3, CMS Pub. 14-3 (Rev. 1780); 42 C.F.R. 415.172 et seq.; Fed. Reg. 63124-01, 1995 WL 723389 (F.R.).)

412. When a teaching physician seeks reimbursement for a service involving a resident in the care of his/her patients, “it must be identified as such on the claim” and is not payable unless it complies with the Claims Processing Manual. (See, CMS 2011 Medicare Claims Processing Manual, 100.1.8 (B) (Physician Billing in the Teaching Setting).)

413. Moreover, the “teaching surgeon must personally document in the medical record that he/she was physically present during the critical or key portion(s) of

³⁴ See, CMS 2011 Medicare Claims Processing Manual, 100.1.2-A.5, Surgical Procedures.

both procedures”. (See, 42 C.F.R. 415.172; CMS 2011 Medicare Claims Processing Manual, 100.1.2 (A) (2), Surgical Procedures.)

414. In sum, the teaching physician must appropriately document his/her involvement in the surgery when the resident performs elements of the surgery in the presence of or jointly with the teaching physician and the documentation must include sufficient information about the work performed during the key portions of both procedures in the notes so that a “reviewer may clearly infer that the teaching physician was immediately available to return to either procedure in the event of complications”. (See, *Goldberg v. Rush Univ. Med. Ctr.*, 929 F. Supp. 807, 823-824 (N.D. Ill. 2013).³⁵

415. Billing for a surgery that does not comply with the above Medicare regulations is a false claim. (See, *Goldberg v. Rush Univ. Med. Ctr.*, *supra*.)

416. Medicare providers are required to make restitution to the Medicare program when overpayments are identified unless the provider is without fault. (See, 42 U.S.C. 1320a-7b(a)(3); see also, 42 C.F.R. 405.350 et seq.; 42 C.F.R. 489.20(b); OIG Compliance Guidance for Hospitals, 63 Fed. Reg. 8987, 8998 (Feb. 23, 1998).)

417. In summary, virtually every claim submitted to Medicare by defendants SAMADI, SAMADI, P.C., LENOX HILL HOSPITAL and NORTHWELL for the simultaneous / concurrent surgeries by unsupervised residents in O.R. 21 during 2013 – 2016 and to the present time is a false claim due to absence of

³⁵ 1996 Rules sec. 15016 (C)(3)(a)(2), Medicare Claims Processing Manual (Transmittal 1780)(November 22, 2002). See, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1780B3.pdf> (last visited April 25, 2017).

SAMADI during the “critical or key portions” of the surgery or the “entire viewing” during endoscopic / laparoscopic urologic procedures.

**Medicare Regulations Pertaining to
Reimbursement for Anesthesia Services**

418. CMS regulations similarly address the issue of anesthesia services by requiring health care providers to follow certain requirements; those requirements are specifically set forth in various authoritative sources defining the Medicare regulations on this issue.³⁶ (See, CMS 2011 Medicare Claims Processing Manual, Payment for Anesthesia Services; 42 U.S.C. §1395y(a)(1)(A).)

419. Medicare reimburses hospitals and anesthesia practitioners for the period of time during which the anesthesiologists or CRNAs are “present with the patient.” (See, CMS 2011 Medicare Claims Processing Manual, Payment for Anesthesia Services.)

420. Specifically, the billing period or “anesthesia time” begins “when the anesthesia practitioner begins to prepare the patient for anesthesia services in the operating room or an equivalent area and ends when the anesthesia practitioner is no longer furnishing anesthesia to the patient, that is, when the patient may be placed safely under postoperative care.” *Id.*

³⁶ See, 42 C.F.R. §482.13 (Condition of participation: Patient’s rights); 42 C.F.R. § 482.13(b)(1)-(2); 42 C.F.R. § 482.13(c)(2); 42 C.F.R. § 482.51(b)(2) (Condition of participation: Surgical services); 42 C.F.R. § 482.24(c)(2)(B)(v) (Condition of participation: Medical record services); CMS State Operations Manual, Regulations and Interpretive Guidelines for Hospitals (Rev. 151; 11-20-15); CMS 2007 Hospital Interpretive Guidelines for Informed Consent; AMA Council on Ethical and Judicial Affairs Opinion E-8.16, “Substitution of Surgeon Without Patient’s Knowledge or Consent”; Ghost Surgery: The Ethical and Legal Implications of Who Does the Operation, Kocher, MS, J Bone Joint Surg Am, 84: 148-150 (2002); American Urological Association Code of Ethics (2014).

421. Furthermore, anesthesia time is a “continuous” time block and the actual amount of time spent with the patient is “reported on the claim” for payment. *Id.*

422. Anesthesia time is divided into 15-minute increments and rounded up to one decimal place for the purposes of computing reimbursement charges and payments. *Id.*

423. The Medicare laws and regulations bar reimbursements for general anesthesia that is not medically indicated or justified because “no payment may be made for any expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury to improve the functioning of a malformed body member.” (See, 42 U.S.C. §1395y(a)(1)(A).)

424. Administering anesthesia to patients while they wait for extended periods for their surgeon to scrub in from another surgery that is “simultaneous” or “concurrent”, i.e., intentionally scheduled and conducted at the same time, is similarly not reimbursable pursuant to 42 U.S.C. §1395y(a)(1)(A).

425. Administering general anesthesia to patients without medical justification or necessity is not reasonable or necessary; it is also dangerous to patient safety.

426. In summary, virtually every claim submitted to Medicare by defendants SAMADI, SAMADI, P.C., LENOX HILL HOSPITAL and NORTHWELL for the simultaneous / concurrent surgeries by unsupervised residents in O.R. 21 during 2013 – 2016 and to the present time is a false claim due to the medically unnecessary use of general anesthesia and unnecessarily prolonged anesthesia time.

Medicare Regulations Pertaining to Adequacy of Informed Consent as a Condition of Program Participation

427. CMS regulations also address the issue of certain requirements that must be followed by health care providers to obtain a proper informed consent from a patient; those requirements are specifically set forth in various authoritative sources defining the Medicare regulations on this issue.³⁷

428. Ensuring that Medicare patients have given adequate informed consent prior to surgery or operative procedures is a condition of participation in the Medicare program. (See, 42 C.F.R. §482.13 (Condition of participation: Patient's rights).)

429. Obtaining a proper informed consent before surgery or an operative procedure is a condition of payment for Medicare claims.

430. Obtaining a proper informed consent before surgery or an operative procedure is also a fundamental element of proper surgical practice; it is an essential component of "medically necessary" treatment.

431. The Senate Finance Committee's report saliently pointed out that CMS's conditions of payment and corresponding interpretive guidelines :

"require hospitals to take certain steps to ensure that patients consent to planned surgeries. For example, this guidance states that a well-designed informed consent policy should include a discussion of a surgeon's possible absence during part of the patient's surgery, during which residents will perform surgical tasks, and that the informed consent policy should assure the patient's right to refuse treatment."

(See, Exhibit V, U.S. Senate, Finance Committee, "Concurrent and Overlapping Surgeries: Additional Measures Warranted", December 6, 2016.)

³⁷ See, 42 C.F.R. 415.172(b); 130 CMR 450.275(D) (Covered Services).

432. Submitting claims for concurrent surgeries where a valid informed consent has not been obtained, much less documented in the patient's file, is material false claim.

433. Defendants have failed to obtain full and proper informed consents consistent with the foregoing principles because doing so would influence or potentially influence a patient's decision against consent to undergoing surgery under such "simultaneous", "concurrent" or "double booked" surgery practices.

434. The matter of informed consent is material because, inter alia, it is an essential step or requirement that permits the planned surgery to proceed which creates the obligation for the payment of claims from the Medicare program.

435. The defendants' failure to obtain a proper informed consent for the foregoing "simultaneous", "concurrent" or "double booked" surgery practices also violates other well established standards of medical ethics.

436. According to the American Medical Association (AMA),

"[a] surgeon who allows a substitute to operate on his or her patient without the patient's knowledge or consent is deceitful. The patient is entitled to choose his or her own doctor and should be permitted to acquiesce or refuse the substitution."

"Under the normal and customary arrangement with patients the operating surgeon is obligated to perform the operation but may be assisted by residents or other surgeons. With consent of the patient, it is not unethical for the operating surgeon to delegate the performance of certain aspects of the operation to the assistant provided this is done under the surgeon's participatory supervision, i.e., the surgeon must scrub. If a resident or other physician is to perform the operation under non-participatory supervision, it is necessary to make full disclosure of this fact to the patient, and this should be evidenced by an appropriate statement in the consent. Under these circumstances, it is the resident or other physicians who become the operating surgeon."³⁸

³⁸ See, AMA Council on Ethical and Judicial Affairs Opinion E-8.16, "Substitution of Surgeon Without Patient's Knowledge or Consent".

437. Peer reviewed medical journal authorities have similarly stated:

“The substitution of an authorized surgeon by an unauthorized surgeon or the allowance of unauthorized surgical trainees to operate without adequate supervision constitutes ‘ghost surgery’. These practices are legally and ethically iniquitous. Ghost surgery flies in the face of case law and violates an individual’s right to control his or her own body and violates that person’s right to information needed to make an informed decision.”³⁹

438. Most important, the Code of Ethics mandated by the American Urological Association pertaining to informed consents states, in pertinent part, as follows:

“I will consider *informed consent* integral to providing appropriate medical or surgical care. I recognize that my patient must be provided with *all of the information necessary to consent* and to make his own choice of treatment, regardless of my own advice or judgment. The information provided must include known risks and benefits, costs, reasonable expectations and possible complications, available alternative treatments and their cost, *as well as the identification of other medical personnel who will be participating directly in the care delivery*. Wherever feasible, I will respect my patient's rights and be limited by the scope of my patient's consent.”

(See, Exhibit X, Letter to Samadi, Samadi Advertisement, AUA Code of Ethics, February 7, 2014 [emphasis added].)

439. SAMADI was specifically given a copy of the AUA’s Code of Ethics and cautioned about adherence to the same on February 7, 2014, in a letter sent to him by the American Urological Association related to an investigation into complaints against him from other physicians regarding extravagant and misleading statements in advertising. (See, Exhibit X, Letter to Samadi, Samadi Advertisement, AUA Code of Ethics, February 7, 2014.)

³⁹ See, Ghost Surgery: The Ethical and Legal Implications of Who Does the Operation, Kocher, MS, J Bone Joint Surg Am, 84: 148-150 (2002).

440. Under the foregoing circumstances, it is clear that defendants submitted false claims to Medicare (and also Medicaid and private commercial health insurers) related to simultaneous / concurrent surgeries by the unsupervised urology residents in O.R. 21 that lacked proper informed consents from the patients under standards of proper surgical practice and medical ethics.

441. “Hospitals are required to be in compliance with the federal requirements set for the Medicare Conditions of Participation (COP) in order to receive Medicare/Medicaid payment.” (See, CMS State Operations Manual, Regulations and Interpretive Guidelines for Hospitals (Rev. 151; 11-20-15).)

442. CMS Medicare Conditions of Participation (COP) include numerous informed consent rules designed to protect Medicare and Medicaid patients.

443. For example, patients must have involvement, *inter alia*, in their own plan of care and be offered the ability to refuse treatment. (See, 42 C.F.R. § 482.13(b)(1) & (2).)

444. Medicare and Medicaid patients also have the “right to receive care in a safe setting.” (See, 42 C.F.R. § 482.13(c)(2).)

445. A “properly executed” consent form must be included in each patient’s chart prior to surgery. (See, 42 C.F.R. § 482.51(b)(2) (Condition of participation: Surgical services); 42 C.F.R. § 482.24(c)(2)(B)(v) (Condition of participation: Medical record services).)

446. CMS’s interpretive guidelines for informed consent highlights the importance of compliance with and the centrality of a proper informed consent to receive payment under Medicare regulations.

447. The CMS 2007 Hospital Interpretive Guidelines for Informed Consent, states that a “well designed consent process” for obtaining an informed consent would, among other things, include:⁴⁰

A description of the proposed surgery, including the anesthesia to be used;

The indications for the proposed surgery;

Material risks and benefits for the patient related to the surgery and anesthesia, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner’s clinical judgment. Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity;

Treatment alternatives, including the attendant material risks and benefits;

The probable consequences of declining recommended or alternative therapies;

Who will conduct the surgical intervention and administer the anesthesia;

Whether physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery, in accordance with the hospital’s policies. Important surgical tasks include: opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, implanting devices and placing invasive lines;

For surgeries in which residents will perform important parts of the surgery, discussion is encouraged to include the following:

That it is anticipated that physicians who are in approved post graduate residency training programs will perform portions of the surgery, based on their availability and level of competence;

That it will be decided at the time of the surgery which residents will participate and their manner of participation, and that this will depend on the availability of residents with the necessary competence; the knowledge

⁴⁰ CMS “Revisions to the Hospital Interpretive Guidelines for Informed Consent”, April 13, 2007, at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCLetter07-17.pdf> (last visited _____, 2017).

the operating practitioner/teaching surgeon has of the resident's skill set; and the patient's condition; and

Whether, based on the resident's level of competence, the operating practitioner/teaching surgeon will not be physically present in the same operating room for some or all of the surgical tasks performed by residents.

448. Under the circumstances, the defendants' failure to obtain a proper informed consent violates well established standards of medical ethics, including those standards set forth by CMS, American College of Surgery, American Medical Association, and American Urological Association; therefore, the lack of informed consent for the simultaneous / concurrent surgeries by unsupervised urology residents in O.R. 21 taints each claim submitted to Medicare related to these surgeries.

449. In summary, virtually every claim submitted to Medicare by defendants SAMADI, SAMADI, P.C., LENOX HILL HOSPITAL and NORTHWELL for the simultaneous / concurrent surgeries by unsupervised residents in O.R. 21 during 2013 – 2016 and to the present time is a false claim due to the lack of a proper informed consent.

Medicare Regulations Pertaining to Adequacy of Medical Records

426. CMS regulations also address the issue of certain requirements that must be followed by health care providers with regard to certifying the accuracy of medical records (e.g., operative reports, anesthesia records, operative case records, etc.) that serve as the basis of the claims for payment submitted to Medicare; those requirements are specifically set forth in various authoritative

sources defining the Medicare regulations on this issue and will be discussed *infra*.⁴¹

427. Medicare regulations require that medical records in surgical procedures, e.g., operative reports, contain the name of the attending surgeon who actually performed the surgery or, alternatively, that the attending surgeon was present for the “critical or key portions” of the surgery or present for the “entire viewing” portion of an endoscopic / laparoscopic surgery. See, 42 C.F.R. 415.172(b); 130 CMR 450.275(D) (Covered Services).

428. The regulations also require that the records specify the identity of an available qualified teaching physician, i.e., “backup attending surgeon”, who was actually available and qualified to take over a surgery from residents when the surgeon was not available or involved in another surgery. See, 42 C.F.R. 415.172(b); 130 CMR 450.275(D) (Covered Services).

429. The medical records related to the “simultaneous”, “concurrent” or “double booked” non-RALP surgeries by the urology residents in O.R. 21, particularly the operative reports, failed to comply with these regulations.

430. Appropriate documentation of medical treatment pertaining to concurrent surgeries is a condition of Medicare reimbursement. *Id.*

431. Appropriate documentation is critical as it helps ensure substantive compliance with Medicare regulations and allow detection of non-compliance with the law related to simultaneous / concurrent surgeries.

432. Defendants submitted false claims to the government for all concurrent surgeries where the surgeon’s records do not comply with these regulations.

⁴¹ See, 31 U.S.C.A. § 3729(a)(1)(A), § 3729 (b)(4).

433. This is starkly illustrated by the operative reports for the TURPs on NADLER and MARKELSON that contain the false statements that SAMADI was the “surgeon” under circumstances when SAMADI could not possibly have been present in O.R. 21 since he was simultaneously performing a RALP in O.R. 25. (See, Exhibit B, LHH Urologic Surgery Database [Samadi], 2013 – 2016; Exhibit G, Operative Report, Peter Nadler, June 22, 2015; Exhibit K, Operative Report, Stephen Markelson, October 30, 2013.)

434. The operative reports for SAMADI’s urologic surgeries at LENOX HILL HOSPITAL that were performed by unsupervised urology residents in O.R. 21 while SAMADI was performing surgeries in O.R. 25 also fail to set forth the identity of a qualified and available back up “teaching physician”, i.e., attending surgeon, to return to O.R. 21 to assist the residents actually performing those surgeries in case of emergency.

435. In summary, virtually every claim submitted to Medicare by defendants SAMADI, SAMADI, P.C., LENOX HILL HOSPITAL and NORTHWELL for the simultaneous / concurrent surgeries by unsupervised residents in O.R. 21 during 2013 – 2016 and to the present time is a false claim due to fraudulent medical records.

Summary Re: Defendants’ Medicare Regulatory Violations

436. During the period 2013 – 2016 and continuing in various permutations to the present, defendants DAVID B. SAMADI, M.D., DAVID B. SAMADI, M.D., P.C., LENOX HILL HOSPITAL, and NORTHWELL HEALTH, INC., conspired

to cause the submission of false claims for Medicare reimbursement to the federal government in violation of 31 U.S.C. §3729, *et seq.*, i.e., the U.S. False Claims Act, and the submission of false claims for Medicaid reimbursement to the State of New York in violation of N.Y. Finance Law §§187-194, i.e., the New York False Claims Act and private health insurers.

437. Specifically, defendants intentionally, knowingly and purposefully billed or caused others to bill CMS for simultaneous surgeries that did not conform in material respects to Medicare rules designed, *inter alia*, to protect patient safety.

438. These violations caused improper billing of Medicare for simultaneous surgeries in which:

Defendant SAMADI, as the attending surgeon and the “teaching physician”, was not present in the O.R. during the majority of the surgery including the “critical or key portions of the procedure” on more than one thousand of his patients.

Defendant SAMADI, as the attending surgeon and the “teaching physician”, was not present in the O.R. during the “entire viewing” portion of endoscopic / laparoscopic surgeries (e.g., RALPs, TURPs, cystoscopies, ureteroscopies, bladder biopsies, etc.) including from “the time of insertion of the endoscope” through “the time of removal of the endoscope” on more than one thousand of his patients.

Defendant SAMADI, as the attending surgeon and the “teaching physician”, arranged to have unsupervised second and third year urology residents perform endoscopic / laparoscopic surgeries (e.g., TURPs, cystoscopies, ureteroscopies, bladder biopsies, etc.) in O.R. 21 on more than one thousand of his patients; neither SAMADI nor another qualified teaching physician was immediately available to assist the residents if needed or in time of emergency.

Defendant SAMADI, as the attending surgeon and the “teaching physician”, arranged to have the endoscopic / laparoscopic surgeries (e.g., TURPs, cystoscopies, ureteroscopies, bladder biopsies, etc.) performed by the unsupervised second and third year urology residents in O.R. 21 on more than one thousand of his patients under general anesthesia that was not medically necessary, justified or indicated; SAMADI ordered general

anesthesia for these operations to conceal from his patients that he was not performing their surgeries.

Defendant SAMADI failed to obtain valid informed consents from more than one thousand of his patients to the simultaneous surgeries because LENOX HILL HOSPITAL's consent forms did not mention that SAMADI was to be involved in another surgery at the same time, did not specifically identify the urology residents that performed the surgeries without supervision, and/or did not specifically state that specific urology residents would be performing the "critical and key portions of the procedure" and performing those portions of the endoscopic / laparoscopic operations constituting the "entire viewing" without proper supervision.

Defendants SAMADI, SAMADI, P.C., LENOX HILL HOSPITAL and NORTHWELL, intentionally, knowingly and purposefully failed to properly document and prepared fraudulent medical records pertaining to the foregoing simultaneous surgeries that falsely indicated that SAMADI had either performed the surgery, was present for the "critical or key portions of the surgery", and/or was present for the "entire viewing" portion of the endoscopic / laparoscopic surgery.

437. Defendants SAMADI, SAMADI, P.C., LENOX HILL HOSPITAL and NORTHWELL intentionally, knowingly and purposefully submitted fraudulent bills or claims to Medicare for payments related to the foregoing simultaneous surgeries with the knowledge and awareness that each such surgery, operation and procedure violated Medicare regulations and constituted unlawful requests for payment from the federal government.

438. Defendants SAMADI, SAMADI, P.C., LENOX HILL HOSPITAL and NORTHWELL were and are fully aware that they have been overpaid by Medicare in connection with the foregoing unlawful requests for payment; however, defendants have not taken the proper steps to satisfy obligations owed to CMS and the federal government.

439. The simultaneous / concurrent surgeries billed to Medicare by defendants SAMADI, SAMADI, P.C., LENOX HILL HOSPITAL and NORTHWELL

during the period at issue are all compromised by at least one or more of the Medicare regulatory violations detailed above if not all such violations.

440. Defendants LENOX HILL HOSPITAL and NORTHWELL not only authorized, approved, permitted, allowed, ratified, enabled, equipped, supported, assisted, encouraged, and promoted SAMADI's fraudulent simultaneous surgeries scheme but ensured that the foregoing violations of Medicare regulations could occur through implementation of the following surgical policies and practices:

Defendants LENOX HILL HOSPITAL and NORTHWELL intentionally, knowingly and purposefully approved, permitted, and allowed SAMADI to schedule and perform simultaneous surgeries in O.R. 25 and O.R. 21 on more than two thousand patients.

Defendants LENOX HILL HOSPITAL and NORTHWELL intentionally, knowingly and purposefully approved, permitted, and allowed SAMADI to schedule and arrange to have surgeries performed in O.R. 21 on more than a thousand patients by unsupervised second and third year urology residents.

Defendants LENOX HILL HOSPITAL and NORTHWELL intentionally, knowingly and purposefully approved, permitted, and allowed SAMADI to schedule and perform simultaneous surgeries in O.R. 25 and O.R. 21 on more than two thousand patients under circumstances that made it impossible for him to be present for "the critical or key portions of the procedure", "immediately available to furnish services during the entire procedure" and present for the "entire viewing" during endoscopic / laparoscopic surgeries from "the time of insertion of the endoscope" through "the time of removal of the endoscope."

Defendants LENOX HILL HOSPITAL and NORTHWELL intentionally, knowingly and purposefully approved, permitted, and allowed SAMADI to schedule and perform simultaneous surgeries in O.R. 25 and O.R. 21 on more than two thousand patients without ensuring that another qualified teaching physician was available to assist unsupervised residents performing surgeries in O.R. 21.

Defendants LENOX HILL HOSPITAL and NORTHWELL intentionally, knowingly and purposefully approved, permitted, and allowed SAMADI to arrange for the simultaneous surgeries performed by unsupervised

residents in O.R. 21 to occur under general anesthesia without medical necessity, justification or indication on more than a thousand patients.

Defendants LENOX HILL HOSPITAL and NORTHWELL intentionally, knowingly and purposefully used consent forms that concealed material facts related to SAMADI's scheduling of simultaneous surgeries on his patients in O.R. 25 and O.R. 21, SAMADI's use of unsupervised second and third year urology residents to perform the simultaneous surgeries in O.R. 21, SAMADI's absence from the O.R. during the "critical and key portions" of the surgery and the "entire viewing" during endoscopic / laparoscopic urological surgeries, and the specific identities of the urology residents performing "critical and key portions" of the surgery and the "entire viewing" portions of endoscopic / laparoscopic surgeries without SAMADI's supervision.

Defendants LENOX HILL HOSPITAL and NORTHWELL intentionally, knowingly and purposefully collaborated and cooperated with SAMADI to submit fraudulent bills to Medicare fully aware of the foregoing regulatory violations related to the simultaneous surgeries.

441. The foregoing pattern of fraudulent conduct by defendants SAMADI, SAMADI, P.C., LENOX HILL HOSPITAL and NORTHWELL was undertaken with the intent, knowledge, awareness, purpose and motivation to increase revenue generation, corporate profits, and physician income and compensation.

442. In summary, defendants SAMADI, SAMADI, P.C., LENOX HILL HOSPITAL and NORTHWELL intentionally, knowingly and purposefully submitted false claims to Medicare that were compromised by the foregoing systemic Medicare regulatory violations related to simultaneous surgeries, unnecessary general anesthesia services, lack of a proper informed consent, and fraudulent record keeping and documentation.

443. CMS annually paid for a significant proportion of the expenses related to SAMADI's urologic surgeries at LENOX HILL HOSPITAL during the period

2013 –2016 since many of SAMADI’s simultaneous surgeries were performed on Medicare patients.

444. If CMS and the federal government had known that the defendants’ simultaneous surgeries practices and other fraudulent conduct described above were not eligible for reimbursement, they would not have paid reimbursement to the defendants under the Medicare program.

445. The UNITED STATES OF AMERICA, through the Medicare program, sustained damages from the false claims submitted by and paid to the defendants including (1) surgeon’s fees, (2) anesthesia services fees, (3) hospital fees (room, board, nursing care, medications, medical supplies, etc.) based on inpatient admissions under fraudulent pretenses to the extent that the foregoing fraud scheme involved Medicare beneficiaries.

446. In order to redress the foregoing Medicare violations on behalf of the UNITED STATES OF AMERICA, plaintiff-relators GEORGE MARKELSON, as Executor of the Estate of STEPHEN MARKELSON, Deceased, and PETER NADLER and LORRAINE WATERS bring this *qui tam* Complaint against the defendants alleging violations under 31 U.S.C. §§ 3729 - 3733, et seq., i.e., False Claims Act, arising from the false claims submitted to Medicare for payment related to the urologic surgical services provided to patients at LENOX HILL HOSPITAL by defendants SAMADI, SAMADI, P.C., LENOX HILL and NORTHWELL during the period 2013 – 2016 and continuing to the present.

THE U.S. FALSE CLAIMS ACT
31 U.S.C. §§ 3729-3733

447. The federal False Claims Act provides that any person who (1) knowingly presents or causes another to present a false or fraudulent claim for payment or approval, or (2) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim is liable for a civil penalty of between \$5,500 and \$11,000⁴² for each such claim, plus three times the amount of the damages sustained by the government pursuant to 31 U.S.C. § 3729(a)(1)(A) & (a)(1)(B).

448. These statutes also both contain a “reverse-false-claims” provision that holds liable persons or corporations who knowingly retain overpayments from the government pursuant to 31 U.S.C. § 3729(a)(1)(G).

FIRST COUNT
U.S. FALSE CLAIMS ACT, 31 U.S.C. § 3729(a)(1)(A)

446. All of the preceding allegations are incorporated by reference in this paragraph.

447. This is a claim for treble damages and civil penalties under 31 U.S.C. § 3729(a)(1)(A), i.e., the False Claims Act.

448. As a result of the foregoing fraudulent scheme, conduct, acts, transactions, occurrences and regulatory violations, the defendants knowingly presented to Medicare, false claims related to simultaneous / concurrent surgeries that did not comply with Medicare regulations due to simultaneous / concurrent surgeries that

⁴² See, Federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L. No. 101-410 section 5 (Oct. 5, 1990), 104 Stat. 890.

were performed by residents without the supervision of the “teaching physician” during “critical or key portions” of the operation or procedure or the “entire viewing” portion of endoscopic / laparoscopic urologic operations or procedures; simultaneous / concurrent surgeries that were performed by residents without the availability of the teaching physician or other designated qualified teaching physician to return to the O.R. for assistance in the event of complications; simultaneous / concurrent surgeries that involved unnecessary anesthesia services; simultaneous / concurrent surgeries that lacked a valid informed consent from the patient; and simultaneous / concurrent surgeries that were not properly documented in the medical records.

449. The UNITED STATES, unaware of the falsity or fraudulent nature of the claims submitted by the defendants, paid for claims that would not have otherwise been allowed.

450. By reason of these payments, the UNITED STATES has been damaged and continues to be damaged in a substantial amount.

SECOND COUNT

U.S. FALSE CLAIMS ACT, 31 U.S.C. § 3729(a)(1)(B)

451. All of the preceding allegations are incorporated by reference in this paragraph.

452. This is a claim for treble damages and civil penalties under 31 U.S.C. § 3729(a)(1)(B), i.e., the False Claims Act.

453. As a result of the foregoing fraudulent scheme, conduct, acts, transactions, occurrences and regulatory violations, the defendants knowingly presented to

Medicare, the defendants knowingly made or used false records and/or statements that caused false claims to be submitted to Medicare.

454. The UNITED STATES, unaware of the falsity or fraudulent nature of the claims submitted by the defendants, paid for claims that would not have otherwise been allowed.

455. By reason of these payments, the UNITED STATES has been damaged and continues to be damaged in a substantial amount.

THIRD COUNT

U.S. FALSE CLAIMS ACT, 31 U.S.C. § 3729(a)(1)(C)

456. All of the preceding allegations are incorporated by reference in this paragraph.

457. This is a claim for treble damages and civil penalties under 31 U.S.C. § 3729(a)(1)(C), i.e., the False Claims Act.

456. Defendants entered into a conspiracy or conspiracies to defraud the UNITED STATES through the foregoing fraudulent scheme, conduct, acts, transactions, occurrences and regulatory violations to knowingly submit false claims related to simultaneous / concurrent surgeries that did not comply with Medicare regulations due to simultaneous / concurrent surgeries that were performed by residents without the supervision of the “teaching physician” during “critical or key portions” of the operation or procedure or the “entire viewing” portion of endoscopic / laparoscopic urologic operations or procedures; simultaneous / concurrent surgeries that were performed by residents without the availability of the teaching physician or other designated qualified teaching

physician to return to the O.R. for assistance in the event of complications; simultaneous / concurrent surgeries that involved unnecessary anesthesia services; simultaneous / concurrent surgeries that lacked a valid informed consent from the patient; and simultaneous / concurrent surgeries that were not properly documented in the medical records.

457. The UNITED STATES, unaware of the falsity or fraudulent nature of the claims submitted by the defendants, paid for claims that would not have otherwise been allowed.

458. By reason of these payments, the UNITED STATES has been damaged and continues to be damaged in a substantial amount.

FOURTH COUNT

U.S. FALSE CLAIMS ACT, 31 U.S.C. § 3729(a)(1)(G)

458. All of the preceding allegations are incorporated by reference in this paragraph.

459. This is a claim for treble damages and civil penalties under 31 U.S.C. § 3729(a)(1)(G), i.e., the False Claims Act.

460. As a result of the foregoing fraudulent scheme, conduct, acts, transactions, occurrences and regulatory violations, the defendants knowingly made, used and/or caused the use of false records and/or statements that are material to an obligation to pay or transmit money by the UNITED STATES.

461. The UNITED STATES, unaware of the falsity or fraudulent nature of the claims submitted by the defendants, paid for claims that would not have otherwise been allowed.

462. By reason of these payments, the UNITED STATES has been damaged and continues to be damaged in a substantial amount.

463. Because defendants have failed to reimburse the federal government for sums they unlawfully received as a result of the foregoing fraudulent scheme, conduct, acts, transactions, occurrences and regulatory violations, the UNITED STATES has been damaged and continues to be damaged in a substantial amount.

PRAYER FOR RELIEF

WHEREFORE, for each of the foregoing FIRST through FOURTH COUNTS, the *qui tam* plaintiff-relators request the following relief from each of the defendants, jointly and severally, pursuant to federal law:

- 1) Three times the amount of damages that the federal government has sustained as a result of the acts of the defendants on each count;
- 2) A civil penalty of not less than \$5,500.00 and not more than \$11,000.00 for each violation of 31 U.S.C. § 3729 and/or for the maximum amount set by law or final rule;
- 3) An award to the Relators of the maximum “relator’s share” allowed pursuant to 31 U.S.C. § 3729;
- 4) An award to the Relators of reasonable attorneys’ fees and costs pursuant to 31 U.S.C. § 3730;
- 5) Interest; and
- 6) Such other and further relief as the Court deems to be just and proper.

Dated: New York, New York
October 2, 2017

Yours, etc.,



JOSEPH LANNI (JL 4234)
THE JACOB FUCHSBERG LAW FIRM, LLP
Attorneys for Plaintiff-Relators
GEORGE MARKELSON, as Executor
of the Estate of STEPHEN
MARKELSON, Deceased, PETER
NADLER and LORRAINE WATERS
500 Fifth Ave., 45th Floor
New York, New York 10110
Tel.: 212.869.3500
Fax: 212.398.1532
j.lanni@fuchsberg.com
jlanni051191@gmail.com
josephlanni@msn.com

TO:

Hon. Jeff Sessions
Attorney General of the United States
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530-0001,

Hon. Joon H. Kim
Acting U.S. Attorney
U.S. Attorney's Office
Southern District of New York
1 St. Andrew's Plaza
New York, NY 10007